UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2008

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 000-31719

POZEN Inc.

(Exact name of registrant as specified in its charter)

Delaware	**62-1657552**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1414 Raleigh Road
Suite 400
Chapel Hill, North Carolina 27517
(Address of principal executive offices, including zip code)

(919) 913-1030
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Securities Exchange Act of 1934. (Check one):
☐ Large Accelerated Filer ☒ Accelerated Filer ☐ Non-Accelerated Filer ☐ Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ Yes ☒ No

The number of shares outstanding of the registrant's common stock as of July 25, 2008 was 29,763,560.

POZEN Inc.
(A Development Stage Company)
FORM 10-Q

For the Three Months Ended June 30, 2008

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc.
(A Development Stage Company)
BALANCE SHEETS
(Unaudited)

	June 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,202,497	$ 37,660,068
Short-term investments	41,025,121	36,282,108
Accounts receivable	9,429,038	2,129,003
Prepaid expenses and other current assets	662,020	1,198,397
Total current assets	82,318,676	77,269,576
Property and equipment, net of accumulated depreciation	84,668	117,485
Total assets	$ 82,403,344	$ 77,387,061
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,387,048	$ 2,536,040
Accrued compensation	983,855	1,392,849
Accrued expenses	5,132,885	3,796,164
Deferred revenue	15,780,058	15,936,125
Total current liabilities	27,283,846	23,661,178
Long-term liabilities:		
Deferred revenue	11,085,044	18,475,074
Total liabilities	38,368,890	42,136,252
Preferred stock, $0.001 par value; 10,000,000 shares authorized, issuable in series, of which 90,000 shares are designated Series A Junior Participating Preferred Stock, none outstanding	—	—
Common stock, $0.001 par value, 90,000,000 shares authorized; 29,763,560, and 29,704,760 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	29,764	29,705
Additional paid-in capital	165,224,731	162,371,437
Accumulated other comprehensive income (loss)	(18,020)	14,540
Deficit accumulated during the development stage	(121,202,021)	(127,164,873)
Total stockholders' equity	44,034,454	35,250,809
Total liabilities and stockholders' equity	$ 82,403,344	$ 77,387,061

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period From Inception (September 26, 1996) Through June 30,
	2008	**2007**	**2008**	**2007**	**2008**
Revenue					
Licensing revenue	$ 24,519,015	$ 3,701,000	$ 28,370,096	$ 7,402,000	$ 126,208,875
Development revenue	8,605,038	8,233,383	12,582,946	12,188,387	37,157,566
Total Revenue	33,124,053	11,934,383	40,953,042	19,590,387	163,366,441
Operating expenses:					
General and administrative	3,142,869	2,924,565	5,991,842	6,155,104	80,361,451
Research and development	17,144,221	13,603,599	30,256,753	20,908,017	218,587,356
Total operating expenses	20,287,090	16,528,164	36,248,595	27,063,121	298,948,807
Interest and other income	497,140	746,706	1,258,404	1,536,019	15,981,822
Income (loss) before income tax expense	13,334,103	(3,847,075)	5,962,851	(5,936,715)	(119,600,544)
Income tax expense	—	—	—	—	(667,000)
Income/(loss)	13,334,103	(3,847,075)	5,962,851	(5,936,715)	(120,267,544)
Non-cash preferred stock charge	—	—	—	—	27,617,105
Preferred stock dividends	—	—	—	—	934,478
Net income/(loss) attributable to common stockholders	$ 13,334,103	$ (3,847,075)	$ 5,962,851	$(5,936,715)	$ (148,819,127)
Basic net income/(loss) per common share	$ 0.45	$ (0.13)	$ 0.20	$ (0.20)	
Shares used in computing basic net income/(loss) per common share	29,759,250	29,502,372	29,741,406	29,485,882	
Diluted net income/(loss) per common share	$ 0.43	$ (0.13)	$ 0.19	$ (0.20)	
Shares used in computing diluted net income/(loss) per common share	30,707,710	29,502,372	30,636,529	29,485,882	

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,		Period from September 25, 1996 (inception) through June 30,
	2008	2007	2008
Operating activities			
Net income/(loss)	$ 5,962,851	$ (5,936,715)	$ (120,267,544)
Adjustments to reconcile net income/(loss) to net cash used in operating activities:			
Depreciation	39,310	46,579	1,066,786
Write-down of impaired assets	—	—	155,576
Bond amortization income	(574,798)	(895,242)	(4,068,431)
Noncash compensation expense	2,693,056	2,681,825	24,742,886
Noncash financing charge	—	—	450,000
Changes in operating assets and liabilities:			
Accounts receivable	(7,300,035)	(4,763,761)	(9,429,038)
Prepaid expenses and other current assets	536,377	553,147	(662,020)
Accounts payable and accrued expenses	3,778,735	3,955,682	11,503,789
Deferred revenue	(7,546,097)	(7,402,000)	26,865,102
Net cash used in operating activities	(2,410,601)	(11,760,485)	(69,642,894)
Investment activities			
Purchase of equipment	(6,493)	(16,351)	(1,307,029)
Purchase of investments	(43,020,061)	(37,153,528)	(216,467,826)
Sale of investments	38,819,288	37,949,375	179,493,116
Net cash provided by (used in) investing activities	(4,207,266)	779,496	(38,281,739)
Financing activities			
Proceeds from issuance of preferred stock	—	—	48,651,850
Proceeds from issuance of common stock	160,296	2,023,560	86,633,265
Proceeds from collections of stockholders' receivables	—	—	1,004,310
Proceeds from notes payable	—	—	3,000,000
Payment of dividend	—	—	(162,295)
Net cash provided by financing activities	160,296	2,023,560	139,127,130
Net increase (decrease) in cash and cash equivalents	(6,457,571)	(8,957,429)	31,202,497
Cash and cash equivalents at beginning of period	37,660,068	26,296,884	—
Cash and cash equivalents at end of period	$ 31,202,497	$ 17,339,455	$ 31,202,497
Supplemental schedule of cash flow information			
Cash paid for interest	$ —	$ —	$ 191,328
Supplemental schedule of noncash investing and financing activities			
Conversion of notes payable to preferred stock	$ —	$ —	$ 3,000,000
Preferred stock dividend	$ —	$ —	$ 772,183
Forfeiture of common stock options and warrants	$ —	$ —	$ 314,179
Conversion of common stock warrants to common stock	$ —	$ —	$ 1,080,001

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)
NOTES TO FINANCIAL STATEMENTS
(Unaudited)

1. Development Stage Company

POZEN Inc. ("we" or "POZEN" or the "Company") was incorporated in the State of Delaware on September 25, 1996 and is operating in a single reportable segment. The Company is a pharmaceutical company focused primarily on products for the treatment of acute and chronic pain and other pain-related conditions. Since inception, the Company has focused its efforts on developing products which can provide improved efficacy, safety or patient convenience in the treatment of acute and chronic pain and pain related conditions. The Company intends to enter into collaboration agreements to commercialize its product candidates, and has entered into, and expects to continue to enter into such collaborations. The Company's licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and the eventual royalty payments based on product sales. Additionally, the Company's development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under its collaboration agreements.

Statement of Financial Accounting Standards Board ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises," states that an enterprise shall be considered to be in the development stage if either planned principal operations have not commenced or planned principal operations have commenced, but there has been no significant revenue therefrom. The Company will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of the Company's product candidates. As of June 30, 2008, the Company had $31.2 million in cash and cash equivalents and $41.0 million in short-term investments. Our operating expenses, net of development revenues, for 2008 and 2009 are expected to increase from the level incurred in 2007. However, we believe that we will have sufficient cash reserves to maintain that level of business activities through 2009 provided that certain development expenses are paid by AstraZeneca AB (AstraZeneca), as outlined in the collaboration and license agreement dated August 1, 2006 between the Company and AstraZeneca, as amended by an agreement effective as of September 6, 2007. The Company's expenses might increase additionally in 2008 and 2009 if any regulatory agency requires the Company to conduct additional clinical trials, studies or investigations in connection with their consideration of the Company's regulatory filings for any of its product candidates. The Company is not currently obligated to make any milestone payments to third parties and does not currently have any other required material payment obligations during that period. However, regulatory delays, such as the Company experienced prior to the approval of the Company's New Drug Application (NDA) for Treximet™ (formerly known as Trexima), as a result of the approvable letters the Company received from the U.S. Food and Drug Administration (FDA) in June 2006 and in August 2007, or unforeseen situations or unforeseen developments in the progress of the Company's existing and future product candidates, may increase the Company's cash requirements beyond its currently assumed needs.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Statements—The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission ("SEC") regulations for interim financial information. These financial statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring accruals) necessary to present fairly the balance sheets, statements of operations and statements of cash flows for the periods presented in accordance with accounting principles generally accepted in the United States. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to SEC rules and regulations. It is presumed that users of this interim financial information have read or have access to the audited financial statements and footnote disclosure for the preceding fiscal year contained in the Company's Annual Report on Form 10-K, filed on March 6, 2008. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2008.

Revenue Recognition—The Company records revenue under two categories: licensing revenues and development revenues. With regard to the licensing revenues, the Company's licensing agreements have terms that include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and royalty payments based on product sales. These agreements are accounted for in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition", as amended by SAB 104, "Revenue Recognition" ("SAB 104"), and Emerging Issues Task Force 00-21 ("EITF 00-21"), "Revenue Arrangements with Multiple Deliverables." The non-refundable portion of upfront payments received under the Company's existing agreements is deferred by the Company upon receipt and recognized on a straightline basis over the period ending on the anticipated date of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on the part of the Company. For the Company's current agreements, these periods are estimated to be as follows:

- The September 2006 $40.0 million licensing fee received from AstraZeneca related to the August 2006 Collaboration and License Agreement with AstraZeneca has been deferred and was being amortized over 40 months. As a result of the revised development timeline agreed upon in the September 2007 amendment, we have extended the amortization period to 43 months. This is a change in accounting estimate and was a prospective adjustment beginning in the third quarter of 2007. The AstraZeneca licensing fee relates to the Company's proprietary fixed dose combinations of the proton pump inhibitor (PPI) esomeprazole magnesium with the non-steroidal anti-inflammatory drug (NSAID) naproxen, in a single tablet. We recognized $2.7 million and $5.5 million of licensing revenue from the amortization of the AstraZeneca licensing fee for the three and six months ended June 30, 2008, respectively. The September 2007 amendment to the AstraZeneca agreement included a $10 million payment in connection with execution of the amendment. This payment has been deferred and will be amortized over 31 months. We recognized $1.0 million and $1.9 million of licensing revenue from this amortization in the three and six months ended June 30, 2008.

- The June 2003 initial licensing and patent-issuance milestone payments totaling $25.0 million for MT 400 received from GSK have been deferred and were originally being amortized over 42 months. During 2005 the amortization period was decreased to 39 months based upon the August 2005 submission to the FDA of the Treximet NDA which was earlier than anticipated. The 2005 change in the amortization period resulted in a $0.7 million increase in the 2005 full-year amortization. During 2006 based upon the June 2006 receipt of an approvable letter from the FDA related to the Treximet NDA and the December 2006 receipt of a notice from the FDA that it had requested additional analyses and supporting information relating to submitted data, $1.9 million of the $25 million initial licensing and patent-issuance milestone payments was deferred to 2007. With the receipt of a second approvable letter in August 2007, unamortized deferred revenue was amortized through March 2008. We recognized $0.0 million and $0.2 million of licensing revenue from the amortization of GSK milestone payments during the three and six months ended June 30, 2008, respectively. The GSK upfront payments are now fully amortized.

- The September 2003 $1.0 million licensing fee for MT 300 ($2.0 million non-refundable upfront licensing fee net of a potential termination fee of $1.0 million) received from Valeant Pharmaceuticals North America (Valeant NA), a subsidiary of Valeant Pharmaceuticals International (formerly Xcel Pharmaceuticals Inc.), has been amortized over 32 months. As the result of the receipt in October 2003 of a not-approvable letter from the FDA relating to the NDA for MT 300, after three months of amortization, this estimated deferral period was increased from an original estimate of 20 months to 32 months ending in April 2006.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement; and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. During the three and six months ended June 30, 2008 a $20.0 million milestone was recognized related to the approval of, and GSK's intent to commercialize, Treximet. There was no milestone revenue recognized for the six months ended June 30, 2007.

Treximet royalty revenue is recognized when earned as will future royalty revenues with respect to the manufacture, sale or use of the Company's products or technology. For Treximet or those future arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and reflect in future revenue any differences between the estimated and actual royalties. During the three and six months ended June 30, 2008, the Company recognized $0.8 million of royalty revenue which is included within licensing revenue in the accompanying statements of operations.

With regards to the development revenues, the Company's licensing agreements may include payment for development services provided by the Company on an hourly rate and direct expense basis. The Company records such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project. In accordance with EITF 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent", under the collaboration agreements with AstraZeneca and GSK, the Company recognizes as development revenue the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described within the related agreements. We recognized $12.6 million and $12.2 million of development revenue for development activities performed pursuant to the AstraZeneca and GSK agreements for the six months ended June 30, 2008 and 2007, respectively. The Company's costs associated with the billed direct costs totaled $7.9 million and $7.2 million for the three months ended June 30, 2008 and 2007, respectively. The Company's costs associated with the billed direct costs totaled $11.0 million and $10.6 million for the six months ended June 30, 2008 and 2007, respectively. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Investments—Investments consist primarily of United States government and government agency obligations, and corporate fixed income securities. The Company invests in high-credit quality investments in accordance with its investment policy, which

minimizes the possibility of loss. Under the Company's investment policy, investments that have a maturity of greater than three months and less than one year are classified as short-term, are considered to be available-for-sale and are carried at fair value with unrealized gains and losses recognized in other comprehensive income (loss). The fair value of the Company's investments and cash equivalents are based upon quoted prices of identical assets which the Company has the ability to access, in active markets, at the measurement date. Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis. Generally, investments with maturities beyond twelve months are classified as long-term. Marketable and non-marketable equity investments are evaluated, on an on-going basis, for market impairment. If it is determined that a decline of any investment is other than temporary, the investment would be written down to fair value and the write-down would be permanent. For the three month period ended June 30, 2008 and 2007, the Company had $0.2 million and $0.3 million, respectively, of interest income and $0.3 million and $0.4 million, respectively, of bond amortization income included in other income for the period. For the six month period ended June 30, 2008 and 2007, the Company had $0.7 million and $0.6 million, respectively, of interest income and $0.6 million and $0.9 million, respectively, of bond amortization income included in other income for the period.

Accumulated Other Comprehensive Income—The Company follows the provisions of SFAS 130, "Reporting Comprehensive Income." SFAS 130 establishes standards for the reporting and display of comprehensive income and its components for general purpose financial statements. Accumulated other comprehensive income is comprised of unrealized gains and losses on marketable securities and is disclosed as a component of stockholders' equity. The Company had $(18,020) unrealized losses on its investments that are classified as accumulated other comprehensive income (loss) at June 30, 2008 and $(4,261) of unrealized losses for the same period of 2007.

Comprehensive income (loss) consists of the following components for the three and six months ended June 30, 2008 and 2007:

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Net income (loss)	$ 13,334,103	$ (3,847,075)	$ 5,962,851	$ (5,936,715)
Unrealized gain (loss) on marketable securities	(47,065)	(2,705)	(32,560)	(169)
Total comprehensive income (loss)	$ 13,287,038	$ (3,849,780)	$ 5,930,291	$ (5,936,884)

Stock-based Compensation—On January 1, 2006, we adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share-Based Payment," which requires us to account for share-based payment transactions using a fair value-based method and recognize the related expense in our results of operations.

Under the fair value recognition provisions of SFAS No. 123(R), stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. Consistent with the valuation method we used for disclosure-only purposes under the provisions of SFAS No. 123, we use the Black-Scholes model to value service condition and performance condition option awards under SFAS No. 123(R). For awards with only service conditions and graded-vesting features, we recognize compensation cost on a straight-line basis over the requisite service period. For awards with performance conditions granted subsequent to our adoption of SFAS No. 123(R), we intend to recognize compensation cost over the expected period to achieve the performance conditions.

Our statements of operations for the three and six months ended June 30, 2008 and June 30, 2007 includes the following stock-based compensation expense:

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Research and development	$ 590,770	$ 305,490	$ 922,676	$ 789,627
General and administrative	1,062,547	750,902	1,770,381	1,725,532
Operating expense	1,653,317	1,056,392	2,693,057	2,515,159
Tax benefit	-	-	-	-
Net expense	$ 1,653,317	$ 1,056,392	$ 2,693,057	$ 2,515,159

Unrecognized stock-based compensation expense, including time-based options, performance-based options and restricted stock awards, expected to be recognized over an estimated weighted-average amortization period of 1.45 years was $9.8 million at

June 30, 2008 and, over an estimated weighted-average amortization period of 1.9 years was $11.0 million at June 30, 2007. Unrecognized stock-based compensation expense expected to be recognized over the remaining period ending December 31, 2008 was $3.1 million at June 30, 2008 and was $2.6 million at June 30, 2007 for the remaining period ending December 31, 2007.

Stock Plans

On November 20, 1996, the Company established a Stock Option Plan (the "Option Plan") and authorized the issuance of options for up to 1,605,310 shares of common stock to attract and retain quality employees and to allow such employees to participate in the growth of the Company. Awards were permitted to be made under the Option Plan to eligible employees, officers, consultants and non-employee directors in the form of incentive or nonqualified stock options. Eligible participants under the Option Plan include executive and key employees of the Company. The vesting periods for options granted under the Option Plan range from immediate vesting at issuance to four years or immediately upon a significant change in ownership as defined by the plan document. The exercise price for incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (110% with respect to incentive stock options granted to optionees who are holders of 10% or more of the Company's common stock).

In June 2000, the stockholders approved the POZEN Inc. 2000 Equity Compensation Plan (the "Plan"). The Plan became effective upon the completion of the Company's initial public offering in October 2000, after which time no further grants were made under the Option Plan. The Plan provides for grants of incentive stock options, nonqualified stock options, stock awards, performance units, and other stock-based awards, such as restricted stock units and stock appreciation rights, to employees, non-employee directors, advisors and consultants. At adoption, the Plan authorized up to 3,000,000 shares of common stock for issuance under the terms of the Plan. The maximum number of shares for which any individual may receive grants in any calendar year is 1,000,000 shares. The vesting periods for awards made under the Plan generally range from immediate vesting at issuance to four years, as described in and in accordance with the Plan, and upon a change of control as defined in the Plan. If options granted under the Plan expire or are terminated for any reason without being exercised, or if stock awards, performance units, or other stock-based awards are forfeited or otherwise terminate, the shares of common stock underlying the grants will again be available for awards granted under the Plan.

In May 2004, the stockholders approved an amendment to and restatement of the Plan. The amendment to the Plan provided for an increase in the number of shares of common stock authorized for issuance under the Plan, from 3,000,000 to 5,500,000, or an increase of 2,500,000 shares. In addition, the amendment to the Plan limited the number of shares that may be issued pursuant to grants other than options under the Plan to 2,000,000 shares and made certain other clarifying changes.

In June 2007, the stockholders approved the amendment and restatement of the Plan to, among other things, increase the number of shares authorized for issuance under the 2000 Plan from 5,500,000 to 6,500,000 shares and continue the various performance criteria for use in establishing specific vesting targets for certain awards under the Plan so as to qualify the compensation attributable to any such awards as performance-based compensation under Section 162(m) of the Internal Revenue Code.

Time-Based Stock Awards

The fair value of each time-based award is estimated on the date of grant using the Black-Scholes option valuation model, which uses the assumptions described below. Our weighted-average assumptions used in the Black-Scholes valuation model for equity awards with time-based vesting provisions granted for the three and six months ended June 30, 2008 and 2007 are shown in the following table:

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Expected volatility	72.9 %	78.8 – 79.2 %	72.9 – 73.2 %	76.0 – 79.2 %
Expected dividends	0 %	0 %	0 %	0 %
Expected term	5.32-6.25 Years	6.25 Years	5.32-6.25 Years	6.25 Years
Risk-free interest rate	3.3 %	4.6 – 4.7 %	2.6 – 3.3 %	4.6 – 5.1 %

A summary of the time-based stock awards as of June 30, 2008, and changes during the six months ended June 30, 2008, is as follows:

Time-Based Stock Awards	Underlying Shares (000s)	Weighted-Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000s)
Outstanding at January 1, 2008	3,445	$ 9.60	6.4	$ 11,167
Granted	311	10.20		
Exercised	(33)	0.33		
Forfeited or expired	-	-		
Outstanding at March 31, 2008	3,723	9.44	6.3	$ 6,509
Exercisable at March 31, 2008	2,406	$ 8.44	5.4	$ 5,836
Granted	35	14.45		
Exercised	(25)	5.29		
Forfeited or expired	-	-		
Outstanding at June 30, 2008	3,733	9.80	5.7	$ 7,813
Exercisable at June 30, 2008	2,419	$ 8.52	5.2	$ 6,800

The aggregate intrinsic value of options outstanding represents the pretax value (the period's closing market price, less the exercise price, times the number of in-the-money options) that would have been received by all option holders had they exercised their options at the end of the period. The exercise price of stock options granted during the six month periods ended June 30, 2008 and 2007 was equal to the market price of the underlying common stock on the grant date. The total intrinsic value of stock options exercised during the three and six months ended June 30, 2008 was $2.1 million and $2.4 million, respectively. The total intrinsic value of stock options exercised during the three and six months ended June 30, 2007 was $1.6 million and $2.3 million, respectively.

Restricted Stock and Restricted Stock Units

As of June 30, 2008, there was an aggregate $224,000 of unrecognized compensation expense related to unvested restricted stock units. Of the aggregate amount, $52,000 unrecognized compensation expense related to unvested restricted stock units under the 2007 award of 20,200 restricted stock units with a grant-date per-share fair value of $16.89 and $172,000 unrecognized compensation expense related to unvested restricted stock units under the May 6, 2008 award of 14,000 restricted stock units with a grant-date per-share fair value of $14.45. As of June 30, 2008, there was no unrecognized compensation expense related to the May 2004 award of 98,135 restricted stock units. There were 17,487 unvested restricted stock units outstanding at June 30, 2008.

Performance-Based Awards

In January 2005, pursuant to an incentive program (the "Treximet incentive program") approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company's employees, including its executive officers, to purchase an aggregate of 506,772 shares of common stock. Each performance-based option would vest in full upon the later to occur of (i) January 3, 2007 or (ii) the receipt by the Company of an action letter from the FDA indicating approval of the NDA for the product candidate Treximet, provided, however that 25% of each such option would be forfeited if receipt of the FDA approval letter for the Treximet NDA did not occur prior to June 30, 2007, and 100% of each such option would be forfeited if receipt of the FDA approval letter for the Treximet NDA did not occur on or before December 31, 2007. These performance-based options, which were granted under the Plan, as amended and restated, had a ten-year term and an exercise price of $7.06, which was equal to the Nasdaq reported market closing price of the common stock on January 3, 2005, the date of grant. The grant date fair value of these performance-based options was $3.77 per share. The receipt of the FDA approval letter for the Treximet NDA had not occurred on or before December 31, 2007 as described under the terms of the initial grant, and therefore all options to purchase shares of common stock under the Treximet incentive program were forfeited during the 2007 year and the related compensation expense was reversed.

On May 6, 2008, pursuant to an incentive program(the "PN incentive program") approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company's employees, including its executive officers, to purchase an aggregate of 281,433 shares of common stock. Twenty-five percent (25%) of the options granted will vest upon the acceptance by the FDA of the NDA for PN 400. The remaining seventy-five (75%) of the options granted will vest upon the receipt by the Company of an action letter from the FDA indicating approval of the NDA for PN 400. The options have a ten-year term and an exercise price of $14.45, which was equal to the Nasdaq reported market closing price of the common stock on May 6, 2008, the date of grant. The weighted grant-date fair value of these performance-based options was $9.66 per share. The options also include provisions that require satisfactory employee performance prior to vesting. An additional 20,000 options were granted to an

executive officer on May 6, 2008 under the PN incentive plan, with identical grant and exercise terms except that 100% of the options granted will vest upon the receipt by the Company of an action letter from the FDA indicating acceptance of the NDA for PN 400.

As of June 30, 2008 and 2007, there were $2.6 million and $38,000, respectively, in unrecognized compensation expense related to performance-based awards granted under the PN and Treximet incentive programs. The June 30, 2008 amount is expected to be recognized over the period ending June 30, 2010, while the June 30, 2007 cost was expected to be recognized over the period ending September 30, 2007. There were 301,433 and 245,560 unvested performance-based options outstanding at June 30, 2008 and 2007, respectively. No performance-based awards were exercised during the three and six months ended June 30, 2008 and 2007; no awards were forfeited during the six months ended June 30, 2008 and 129,691 awards were forfeited during the three and six months ended June 30, 2007. At June 30, 2008 the performance-based options had no intrinsic value and a remaining contractual life of 9.8 years, while at June 30, 2007 the performance-based options had an intrinsic value of $2.7 million and a remaining contractual life of 7.5 years.

The fair value of each performance-based option granted under the Plan, including those granted under the Treximet incentive program, was estimated as of the grant date using the Black-Scholes option valuation model without consideration of the performance measures.

Income and Net Loss Per Share—Basic and diluted net income and net loss per common share amounts are presented in conformity with SFAS 128, "Earnings per Share," for all periods presented. During the six months ended June 30, 2008 and 2007, the Company had potential common stock equivalents related to its outstanding stock options. These potential common stock equivalents were not included in diluted loss per share for the three and six months ended June 30, 2007 because the effect would have been antidilutive and, in accordance with SFAS 128, basic and diluted net loss per common share has been computed using the weighted-average number of shares of common stock outstanding for the three and six months ended June 30, 2007. Accordingly, basic and diluted net loss per share is the same for the three and six months ended June 30, 2007.

In accordance with SFAS 128, the Company has excluded the impact of any shares which might be issued under the Rights Plan, detailed below, from the EPS calculation because the Rights are not exercisable since the specified contingent future event has not occurred.

The following table reconciles the numerator and denominator used to calculate diluted net income per share (in thousands) for the 2008 periods shown:

	Three months ended June 30, 2008	Six months ended June 30, 2008
Numerator:		
Net income	$ 13,334,103	$ 5,962,851
Denominator:		
Weighted average common shares, basic	29,759,250	29,741,406
Dilutive effect of stock options	948,460	895,123
Weighted average common shares, diluted	30,707,710	30,636,529

Rights Plan/Series A Junior Participating Preferred Stock—In January 2005, the Company approved a stockholder rights plan (the "Rights Plan"), pursuant to which the Company entered into a Rights Agreement dated January 12, 2005 with StockTrans, Inc., as Rights Agent, and the Company declared a dividend of a right to acquire one preferred share purchase right (a "Right") for each outstanding share of the Company's Common Stock, $0.001 par value per share, to stockholders of record at the close of business on January 28, 2005. Generally, the Rights only are triggered and become exercisable if a person or group acquires beneficial ownership of 15 percent or more of the Company's common stock or announces a tender offer for 15 percent or more of the Company's common stock. The Rights Plan is similar to plans adopted by many other publicly-traded companies. The effect of the Rights Plan is to discourage any potential acquirer from triggering the Rights without first convincing POZEN's Board of Directors that the proposed acquisition is fair to, and in the best interest of, the shareholders and the Company. The provisions of the Plan will substantially dilute the equity and voting interest of any potential acquirer unless the Board of Directors determines that the proposed acquisition is in the best interest of the shareholders. In connection with the Plan, the Company designated 90,000 shares of its authorized Preferred Stock as Series A Junior Participating Preferred Stock. Each Right, if and when exercisable, will entitle the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, $0.001 par value per share, at a purchase price of $80.00 for each one one-thousandth of a share, subject to adjustment. Each holder of a Right (except for the Acquiring Person (as defined in the Rights Plan), whose Rights will be null and void upon such event) shall thereafter have the right to receive, upon exercise, that number of shares of Common Stock of the Company (or, in certain circumstances, cash, property or other securities of the Company) which equals the exercise price of the Right divided by 50% of the current market price (as defined in the Rights Agreement) per share of Common Stock at the date of the occurrence of such event. The

Rights can be terminated by POZEN's Board of Directors and are subject to optional redemption by the Company at $0.001 per Right. The Rights Plan has a 10-year term and contains provisions requiring a periodic review and evaluation by the Board of Directors.

New Accounting Pronouncements—In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 provides a common definition of fair value and establishes a framework to make the measurement of fair value in generally accepted accounting principles more consistent and comparable. SFAS 157 also requires expanded disclosure to provide information about the extent to which fair value is used to measure assets and liabilities, the methods and assumptions used to measure fair value, and the effect of fair value measures on earnings. SFAS 157 is effective for the Company's 2008 fiscal year. SFAS 157 did not have a material impact on the Company's financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 gives the Company the irrevocable option to carry most financial assets and liabilities at fair value, with changes in fair value recognized in earnings. SFAS 159 is effective for the Company's 2008 fiscal year. SFAS 159 did not have a material impact on the Company's financial statements.

In June 2007, the FASB issued Emerging Issues Task Force ("EITF") on EITF Issue No. 07-3, *"Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities"* ("EITF 07-3"). EITF 07-3 requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties, and amortize them over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company believes EITF 07-3 does not have a material impact on its financial statements.

Contingencies—A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of its securities against the Company, its chairman and chief executive officer and one of its directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, the Company received the plaintiffs' amended and consolidated complaint which added two current officers of the Company as additional defendants. The Company and individual defendants filed motions to dismiss the amended and consolidated complaint with the Court on June 26, 2008. The Company and the individual defendants believe that the plaintiffs' allegations are without merit, and intend to defend these claims vigorously.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the pending class action lawsuit described above. Furthermore, we will have to incur expenses in connection with this lawsuit, which may be substantial. In the event of an adverse outcome, our business could be materially harmed. Moreover, responding to and defending the pending litigation will result in a significant diversion of management's attention and resources and an increase in professional fees.

Under its commercialization collaboration with Valeant NA, related to MT 300, if the Company chooses to withdraw the MT 300 NDA for commercial or financial reasons under the conditions specified in the agreement, it could be required to pay a withdrawal fee of $1.0 million. As a result of this contingency, $1.0 million of the $2.0 million upfront payment received by the Company from Valeant NA pursuant to the agreement has not been recognized as revenue and will not be recognized as revenue until the conditions in the agreement have been satisfied or resolved.

On July 21, 2005, the Company received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee. The Company does not believe the withdrawal fee is payable. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has indicated its intention to pursue the dispute resolution provisions provided for in the agreement. The Company intends to vigorously defend its position under the agreement. At this time, it is not possible to determine if any withdrawal fee will be required to be paid to Valeant NA when the ultimate resolution of this dispute is reached, however, it is the current judgment of management that no reserve is required.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This discussion of our financial condition and the results of operations should be read together with the financial statements, including the notes contained elsewhere in this Form 10-Q, and the financial statements, including the notes thereto, contained in our Annual Report on Form 10-K for the year ended December 31, 2007, as filed on March 6, 2008.

This report includes "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. The forward-looking statements are subject to a number of risks and uncertainties which are discussed below in the section entitled "Item 1A --Risk Factors." We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements, other than as is required under the federal securities laws.

Overview

We are a pharmaceutical company focused on developing products which can provide improved efficacy, safety or patient convenience in the treatment of acute and chronic pain and pain related conditions. We operate a business model that focuses on the following:

- obtaining patents for innovative ideas which we believe have value in the marketplace;
- utilizing a small group of talented employees to develop those ideas through proof of concept by working with strategic outsource partners; and
- licensing the resulting product or technology to a strong pharmaceutical partner to commercialize.

We hire experts with strong project management skills in the specific disciplines we believe are important to maintain within our company. We contract with and manage strong outsource partners as we complete the necessary development work, permitting us to avoid incurring the cost of buying or building laboratories, manufacturing facilities or clinical research operation sites. This allows us to control our annual expenses, but to utilize "best in class" resources as required.

After we establish the proof of concept for an innovative idea, we work with the U.S. Food and Drug Administration, or FDA, or foreign regulatory agencies to design a clear path forward to the filing of a new drug application, or NDA, or its foreign equivalent. We then seek a strong pharmaceutical partner to license the product or technology, to collaborate with us in the remaining development and to commercialize the product or technology after approval. The success of our business is highly dependent on the marketplace value of our ideas and the related patents we obtain, our ability to obtain from the required regulatory agencies approval to sell the developed products and our ability to find strong commercial partners to successfully commercialize the products.

We have developed Treximet™ (formerly known as Trexima™) in collaboration with GlaxoSmithKline, or GSK. Treximet is the brand name for the product combining sumatriptan 85 mg, formulated with RT Technology™ and naproxen sodium 500 mg in a single tablet designed for the acute treatment of migraine. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults. Upon receipt of FDA approval, GSK notified us of its intention to launch the product and Treximet was available in pharmacies in May 2008.

Treximet incorporates our MT 400 technology, which refers to our proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a non-steroidal anti-inflammatory drug, or NSAID. Under our MT 400 technology, we sought to develop product candidates that provide acute migraine therapy by combining the activity of two drugs that act by different mechanisms to reduce the pain and associated symptoms of migraine. We filed the NDA for Treximet with the FDA in August 2005 and in June 2006, we received an approvable letter requiring us to provide certain additional safety information relating to Treximet, some of which required new studies. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. In early February 2007, we delivered a full response to this approvable letter that provided additional data and analyses and supporting information addressing the FDA's safety concerns, including cardiovascular safety. On August 1, 2007, we received a second approvable letter from the FDA for Treximet in which the FDA requested that we further address the FDA's concern about the product's potential for genotoxicity. In response to this approvable letter, we submitted the results of three non-clinical (in vitro) studies that provided clarifying information about the Chinese Hamster Ovary, or CHO, assay and data from a clinical evaluation of the genotoxic potential of Treximet in human volunteers which indicated that no chromosomal aberrations were induced in peripheral blood lymphocytes when Treximet was administered to volunteers for seven days. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults.

We are also developing product candidates that combine a type of acid inhibitor, a proton pump inhibitor, or PPI, with an NSAID (our PN program). These product candidates are intended to provide management of pain and inflammation associated with conditions such as osteoarthritis, and are intended to have fewer gastrointestinal complications compared to an NSAID taken alone.

In August 2006, we entered into an exclusive global collaboration and license agreement with AstraZeneca AB, or AstraZeneca, to co-develop and commercialize proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet using our PN formulation technology, which agreement was amended in September 2007. We began the Phase 3 program in September 2007. As part of the program, we are conducting two Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers. In addition, we are conducting a long-term, open label safety study. We have terminated a non-pivotal smaller study in patients at high risk of gastrointestinal related events from NSAIDs which we believe is not required for approval. We are also conducting additional studies at AstraZeneca's expense.

Another product candidate, PA, a combination of a PPI and aspirin, is currently in formulation and clinical development testing. Our PA product candidates are excluded from our agreement with AstraZeneca. We have met with the FDA and confirmed that the development program for PA32540 will be similar to our PN product development program. The objective of the program will be to establish that patients taking our PA32540 product have fewer gastric ulcers than patients taking enteric coated, or EC, 325 mg aspirin over the study treatment period. An investigational new drug application, or IND, was filed in the fourth quarter of 2007. we have completed a study which demonstrated the bioequivalence of PA32540 as compared to 325 mg of enteric coated aspirin and filed a Special Protocol Assessment (SPA) with the FDA for the design of the Phase 3 studies for the product, which could begin as early as the second half of 2008.

We are also conducting both formulation development and early stage clinical studies with new product concepts that are currently in the exploratory stage. If warranted, we may file U.S. and international patent applications with claims directed toward these novel combinations and formulations.

We have incurred significant losses since our inception and have not yet generated significant revenue from product sales. As of June 30, 2008, our accumulated deficit was approximately $121.2 million. We record revenue under two categories: licensing revenues and development revenues. The Company's licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and the royalty payments based on product sales. Additionally, the Company's development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under its collaboration agreements. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented approximately 73% of our total operating expenses. For the six months ended June 30, 2008, our research and development expenses represented approximately 83% of our total operating expenses.

Statement of Financial Accounting Standards Board (SFAS) No. 7, "Accounting and Reporting by Development Stage Enterprises," states that an enterprise shall be considered to be in the development stage if either planned principal operations have not commenced or planned principal operations have commenced, but there has been no significant revenue therefrom. We will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of our product candidates.

We expect that we may continue to incur operating losses over the next several years as we complete the development and seek regulatory approval for our product candidates, develop other product candidates and acquire and develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- The progress of our PN and PA product candidates and our other product candidates in the clinical and regulatory process;

- The ability of GSK to successfully launch and commercialize Treximet in the U.S. For example, Treximet was available in pharmacies within one month from the date of its approval, but initial promotional materials for the product, including direct to consumer advertising, has not yet been approved by the FDA. The lack of approved materials and advertising at launch may have had an adverse impact on initial sales of the product, thus affecting our royalty revenue during the second quarter. GSK has not yet received approval of the promotional materials from the FDA, which may negatively impact our royalty revenue in the third quarter;

- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates; and

- The acquisition and/or in-licensing, and development, of other therapeutic product candidates.

We do not currently have commercialization or manufacturing capabilities. We have entered into collaborations and currently plan to enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. Our ability to generate revenue is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, and successfully develop product candidates, obtain regulatory approvals and successfully manufacture and commercialize our future products. These milestones are earned when we have satisfied the criteria set out in our revenue recognition footnote accompanying the financial statements included elsewhere in this Annual Report on Form 10-K. These payments generate large non-recurring revenue that will cause large fluctuations in quarterly and annual profit and loss.

Status of Our Product Candidates

There follows a brief discussion of the status of each of our product candidates, as well as the costs relating to our development activities. Our research and development expenses that are not direct development costs consist of personnel and other research and development departmental costs and are not allocated by product candidate. We do not maintain records that allocate our employees' time by the projects on which they work and, therefore, are unable to identify costs related to the time that employees spend on research and development by product candidate.

MT 400/Treximet

On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults. GSK notified us of its intention to launch the product and was available in pharmacies in May 2008. As part of our NDA program for Treximet, we conducted five Phase 1 trials, two Phase 3 pivotal trials, and one 12-month open label safety trial using a formulation of Treximet developed by GSK. The Phase 3 pivotal trials, including the endpoints required to evaluate Treximet, were designed to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Additionally, the program was designed to demonstrate that each component makes a contribution to the efficacy of Treximet (the "combination drug rule" that the FDA requires of all combination products). The efficacy endpoint for the combination was sustained pain free, which is defined as improvement from moderate or severe pain to no pain at two hours and remaining at no pain through twenty four hours without the use of rescue medicine. Further, GSK continues to conduct market support studies for Treximet. As required by the terms of our agreement with GSK, we transferred ownership of the NDA and other regulatory filings for Treximet to GSK on May 14, 2008 and GSK now has responsibility for all ongoing regulatory obligations for the product, including post marketing clinical trial requirements.

We incurred $0.2 million in direct development costs associated with the development of MT400/Treximet for the six months ended June 30, 2008 and have incurred $25.7 million in costs from inception to date. In the three and six month periods ended June 30, 2008, we received $20.0 million in milestone payments from GSK for the approval of, and GSK's intent to commercialize Treximet and we accrued $0.8 million of Treximet royalty revenue. We billed GSK $0.2 million for Treximet activities for the six months ended June 30, 2008 and billed $2.1 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

PN Program

Under our PN program, we have completed formulation development and clinical studies for several combinations of a PPI and an NSAID in a single tablet intended to provide effective management of pain and inflammation associated with chronic conditions such as osteoarthritis, and intended to have fewer gastrointestinal complications compared to an NSAID taken alone in patients at risk for developing NSAID associated gastric ulcers. We initially conducted studies with two PN product formulations in this program - PN 100, a combination of the PPI lansoprazole and the NSAID naproxen, and PN 200, a combination of the PPI omeprazole and naproxen, prior to entering into our collaboration with AstraZeneca. Our present development and commercialization efforts under the PN program are covered under our exclusive collaboration agreement with AstraZeneca, which we entered into on August 1, 2006 and which was amended in September 2007. Under our agreement with AstraZeneca, we and AstraZeneca are co-developing, and AstraZeneca will commercialize, proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet. The initial product to be developed under the agreement, PN 400, is being studied for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID-associated gastric ulcers. On March 2, 2007, we filed an IND with the FDA for PN 400 and in April 2007, the first Phase 1 study was initiated.

In discussions with the FDA during 2005 regarding our development plans for studies to pursue FDA approval of PN 100 and PN 200, the FDA agreed that by including naproxen as the NSAID within the PN formulation, we could expect that all indications for chronic use of naproxen in adults would accrue to the PN product, if clinical trials successfully demonstrated improved safety (lower incidence of gastric ulcers) of the PN product compared with naproxen alone and the PN formulation was shown to be bioequivalent

to marketed formulations of EC naproxen. Prior to entering into our collaboration agreement with AstraZeneca, we completed a study designed to demonstrate the bioequivalence of the naproxen component of our PN 200 product candidate development formulation to EC naproxen. This study demonstrated that the PN 200 product was bioequivalent to the reference drug, EC Naprosyn® with respect to the naproxen component.

In early 2006, we submitted a Special Protocol Assessment, or SPA, to the FDA for our pivotal Phase 3 clinical trials for PN 200. The SPA is a process in which the FDA provides evaluations and guidance on clinical trial protocols for pivotal Phase 3 clinical trials. In April 2006, we announced that we had reached an agreement with the FDA on the Phase 3 pivotal clinical trials for PN 200 for the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing NSAID-associated gastric ulcers. We also reached agreement with the FDA that the development program and study design proposed for PN 200 would be applicable to a product that contained an isomer of omeprazole combined with naproxen. In light of our collaboration agreement with AstraZeneca, we, along with AstraZeneca have met with the FDA and confirmed the core development program and the SPA already agreed upon do apply to the new product consisting of proprietary fixed dose combinations of esomeprazole magnesium with naproxen.

In the third quarter of 2006, we began recruiting subjects for a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy. The primary endpoint for the trial was the cumulative incidence of gastric ulcers over six months of treatment. Because we did not have final results until the fourth quarter of 2007, we, together with AstraZeneca reviewed the interim results of this trial prior to commencing Phase 3 studies of PN 400 in September 2007. This study has now been completed and the results, which indicated significantly fewer endoscopically confirmed gastric ulcers during the six month treatment period in subjects on PN 200 compared to subjects receiving enteric coated naproxen alone, have been presented publicly. We are currently conducting two PN 400 Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers. In addition, we are conducting a long-term, open label safety study. We have terminated a non-pivotal smaller study in patients at high risk (i.e., previous bleeding from a gastric ulcer) of gastrointestinal related events from NSAIDs which is not required for approval. We are also conducting additional studies at AstraZeneca's expense.

In 2005, we also had discussions with the FDA concerning the implications of the FDA's guidance issued in June 2005 concerning labeling of NSAID-containing products, which resulted from an FDA advisory committee meeting held in February 2005. The advisory committee addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX-2 selective NSAIDs. Based on our discussions with the FDA reviewing division for PN products, we believe that, unless new information about naproxen safety concerns becomes available, long-term cardiovascular safety studies will not be required at this time for FDA approval of our PN product candidates containing naproxen. However, we cannot guarantee that such studies will not be required. We will continue to evaluate and review with the FDA its expectations and recommendations regarding the efficacy and safety requirements and study design necessary to support approval of NDAs for our PN product candidates.

Additionally, we have met with four national European regulatory agencies to discuss the proposed development program for PN. While further clarification will be needed based on the intention to develop the esomeprazole combination, further clinical studies, beyond those specifically required for the NDA submission in the U.S., will likely need to be conducted. In part, these studies will be required as the naproxen-containing products on the European market differ in strength and formulation from those available in the U.S. Under our agreement with AstraZeneca, AstraZeneca has responsibility for the development program for PN outside the U.S., including interactions with regulatory agencies.

We cannot reasonably estimate or know the amount or timing of the costs necessary to obtain regulatory approval of PN 400. Nor can we reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any PN product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PN products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our PN program of $23.4 million for the six months ended June 30, 2008 and we have incurred $66.5 million from inception to date, $35.1 million of which was funded by development revenue from AstraZeneca. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

PA Program

As part of our PA program, we are exploring the development of a combination of a PPI and aspirin in a single tablet. Similar to the PN program, our PA product candidate is intended to induce fewer gastrointestinal complications compared to an aspirin taken alone in patients at risk for developing aspirin associated gastric ulcers. Our PA product candidates are covered under the same patent as PN, but we have retained all rights to this program.

Our initial PA product candidate, PA32540, is currently in early-stage clinical development. We completed a Phase 1 proof of concept study in Canada of an earlier formulation of PA containing 325 mg of aspirin and 20 mg of omeprazole (PA32520) in the first quarter of 2007. The primary endpoint was gastrointestinal damage as measured by the Lanza scoring system used in our previous PN studies. The results were highly significant ($p<0.001$) with 10 percent of the PA group having Lanza 3 or 4 gastrointestinal damage, whereas 57.5% of the EC aspirin group had this level of gastrointestinal damage during the 28 day study. We also completed a second proof of concept study with PA32520 as compared to 81 mg of EC aspirin. These results confirmed the earlier levels of gastric damage as measured by Lanza scoring at about 10% for PA32520. While these results in the second study were numerically different between treatment groups, they did not achieve statistical significance from the results obtained with 81mg EC aspirin (21%). After reviewing these data, we decided to increase the dose of omeprazole to 40 mg per tablet and conduct an additional 28 day Phase 1 study using the formulation containing 40 mg of immediate release of omeprazole and 325 mg of aspirin (PA32540) compared to 325 mg EC aspirin. Topline results from this study indicate a highly significant ($P=0.003$) reduction in gastro intestinal damage with the higher strength PA32540 tablet as compared with 325 mg EC aspirin (2.5% vs 27.5% grade 3 or 4 Lanza scores, respectively). In this last study, 75% of subjects treated with the PA32540 tablet showed no gastrointestinal damage at all as compared to < 50% with the PA32520 tablet. We met with the FDA in July 2007 and confirmed that the development program for PA will be similar to our PN product development program. The objective of the program will be to provide a cardioprotective form of aspirin that causes fewer gastric ulcers than aspirin alone. As a step toward achieving that goal, we completed a study which demonstrated that PA32540 was bioequivalent to the reference drug, EC aspirin, with respect to the aspirin component, and which we believe will allow our PA product to receive all the cardio- and cerebrovascular secondary prevention claims of aspirin. In the Phase 3 studies for the product, we must establish that patients taking our PA32540 product have fewer gastric ulcers than patients taking EC 325 mg aspirin over the six month study treatment period. An IND was filed in the fourth quarter of 2007 and Phase 3 studies could commence as early as the second half of 2008.

We cannot reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any PA product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PA products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our PA program of $2.7 million during the six months ended June 30, 2008, and we have incurred $10.2 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 300

In October 2003, we received a not-approvable letter from the FDA related to our NDA for MT 300, which we had submitted in December 2002. We are not currently conducting any clinical trials for MT 300 and do not expect to incur any additional significant development costs related to MT 300, nor do we believe that we will receive any future cash inflows from MT 300. We incurred no direct development costs associated with the development of MT 300 for the six months ended June 30, 2008, and we have incurred $14.7 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

In July 2005, we received a letter from our partner, Valeant NA, seeking payment of a $1.0 million withdrawal fee required under certain conditions under the agreement. Under the agreement, if we determine that additional studies or data that are required by the FDA for approval of the NDA for MT 300 would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300, we may elect to withdraw the NDA. If we notify Valeant NA of this situation and Valeant NA elects not to assume control of efforts to seek approval of the NDA, then, under the conditions outlined in the agreement, upon notice from Valeant NA, the agreement will terminate and we would be required to pay Valeant NA a termination fee of $1.0 million. If Valeant NA decides to assume development, it would be credited $1.0 million in development expense. We do not believe that the withdrawal fee is payable under the circumstances of receipt of the not-approvable letter from the FDA. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for under the agreement. We can give no assurance that Valeant NA will agree to termination terms acceptable to us, or that we will not be required to pay Valeant NA the withdrawal fee described above.

Collaborative Arrangements

We have entered into and plan to continue to enter into collaborations with established pharmaceutical or pharmaceutical services companies to develop, commercialize and/or manufacture our product candidates. Our existing collaborations are described below.

GlaxoSmithKline (GSK)

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the U.S. to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. We were responsible for development of the first combination product, while GSK provided formulation development and manufacturing. Pursuant to the terms of the agreement, we received $25.0 million in initial payments from GSK following termination of the waiting period under the Hart-Scott-Rodino notification program and the issuance of a specified patent. In May 2004, we received a $15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. In October 2005, we received a $20.0 million milestone payment upon the FDA's acceptance for review of the NDA for Treximet, the trade name for the product. On April 26, 2008 the Company received, from GSK, $20.0 million in milestone payments which were associated with the approval of, and GSK's intent to commercialize, Treximet. In addition, GSK will pay us two sales performance milestones totaling $80.0 million if certain sales thresholds are achieved. Up to an additional $10.0 million per product is payable upon achievement of milestones relating to other products. At June 30, 2008, the Company accrued $0.8 million of Treximet royalty revenue and GSK will also pay us royalties on all net sales of marketed products until at least the expiration of the last to expire issued applicable patent (August 14, 2017) based upon the scheduled expiration of currently issued patents). GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre-determined share of the market for the combination product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle us to terminate the agreement is GSK's determination not to further develop or to launch the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

AstraZeneca AB (AstraZeneca)

In August 2006, we entered into a collaboration and license agreement dated as of August 1, 2006 and effective September 7, 2006 with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers. Under the terms of the agreement, we granted to AstraZeneca an exclusive, fee-bearing license, in all countries of the world except Japan, under our patents and know-how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). AstraZeneca may, at no additional cost, elect to include Japan in the licensed territory within two years after the effective date of the agreement. Pursuant to the terms of the agreement, we received an upfront license fee of $40.0 million from AstraZeneca following termination of the waiting period under the Hart-Scott-Rodino notification program.

In September 2007, we agreed with AstraZeneca to amend our collaboration and license agreement effective as of September 6, 2007. Under the terms of the amendment, AstraZeneca has agreed to pay us up to $345.0 million, in the aggregate, in milestone payments upon the achievement of certain development, regulatory and sales events. In September 2007 we received a $10.0 million payment upon execution of the amendment and a $20.0 million payment in recognition of the achievement of successful proof of concept. An additional $55.0 million will be paid upon achievement of certain development and regulatory milestones, and $260.0 million will be paid as sales performance milestones if certain aggregate sales thresholds are achieved. Under the original agreement, we were to have received development and regulatory milestones totaling $160.0 million, of which $20.0 million was to be paid upon the successful completion of the proof of concept studies, and sales performance milestones totaling $175.0 million.

In addition, the amendment revised the royalty rates we were to have received under the original agreement. Under the original agreement, we were to receive a royalty based on annual net sales by AstraZeneca, its affiliates or sublicensees during the royalty term. The royalty rate varied based on the level of annual net sales of products made by AstraZeneca, its affiliates and sublicensees, ranging from the mid-single digits to the mid-teens. Under the Amendment, we will now receive a flat, low double digit royalty rate during the royalty term on annual net sales of products made by AstraZeneca, its affiliates and sublicensees, in the U.S. and royalties ranging from the mid-single digits to the high-teens on annual net sales of products made by AstraZeneca, its affiliates and sublicensees outside of the U.S. The amendment also revises the rate of reduction to the royalty rate based upon loss of market share due to generic competition inside and outside of the U.S. to account for the new royalty structure.

Our right to receive royalties from AstraZeneca for the sale of such products under the collaboration and license agreement, as amended, expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights relating to such products in that country, and (b) ten years after the first commercial sale of such products in such country.

We retain responsibility for the development and filing of the NDA for the product in the U.S. AstraZeneca is responsible for all development activities outside the U.S., as well as for all manufacturing, marketing, sales and distribution activities worldwide. We have agreed to bear all expenses related to certain specified U.S. development activities. All other development expenses, including all manufacturing-related expenses, will be paid by AstraZeneca. The agreement established joint committees with representation of both us and AstraZeneca to manage the development and commercialization of the product. The committees operate by consensus, but if consensus cannot be reached, we generally will have the deciding vote with respect to development activities required for marketing approval of the product in the U.S. and AstraZeneca generally will have the deciding vote with respect to any other matters.

The agreement, unless earlier terminated, will expire upon the payment of all applicable royalties for the products commercialized under the agreement. Either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement, elect to transfer the product and all rights to us.

Valeant Pharmaceuticals North American (Valeant NA) (formerly Xcel Pharmaceuticals Inc.)

In September 2003, we signed an agreement with Valeant NA for the further development and commercialization of MT 300. In March 2005, Valeant Pharmaceuticals International (Valeant International) acquired Valeant NA. Under the terms of the agreement, Valeant NA would have exclusive rights in the United States to commercialize MT 300 subject to certain minimum commercialization obligations. Pursuant to the terms of the agreement, Valeant NA paid us an upfront fee of $2.0 million. Upon certain future regulatory approvals, including the FDA's approvals relating to MT 300, and the achievement of a predetermined sales threshold on MT 300, potential milestone payments of up to $8.0 million would be due. Valeant NA is also obligated to pay us royalties on all combined net sales of MT 300 and Valeant NA's D.H.E. 45® (dihydroergotamine mesylate) Injection, upon commercialization of MT 300, until at least the expiration of the last to expire issued applicable patent (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent), subject to reduction in certain instances of generic competition, or in the event that Valeant NA pays royalties to one or more third parties to license rights from such third parties to commercialize MT 300. The agreement terminates on the date of expiration of all royalty obligations (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent) unless earlier terminated by either party for a material breach or in the event that either party determines not to pursue approval of MT 300, under the conditions described below. Under certain circumstances, the agreement provides for the terminating party to facilitate the assumption of its responsibilities by the non-terminating party. Generally, each party must indemnify the other for damages arising from such party's breach of its representations, warranties and obligations under the agreement, as well as for the gross negligence or willful misconduct by either party. Additionally, Valeant NA must indemnify us for damages arising from the development, manufacture or use of any product after the effective date of the agreement, while we must indemnify Valeant NA for any damages arising from such development, manufacture or use prior to the effective date. We must also indemnify Valeant NA for any use by us or any sub licensee of certain technology owned by Valeant NA.

Under the agreement, if we determine that additional studies or data that are required by the FDA for approval of the NDA for MT 300 would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300, we may elect to withdraw the NDA. If we notify Valeant of this situation and Valeant NA does not assume control of efforts to seek approval of the NDA, then, under the conditions outlined in the agreement, upon notice from Valeant NA the agreement will terminate and we would be required to pay Valeant NA a withdrawal fee of $1.0 million. If Valeant decides to assume development, it would be credited $1.0 million in development expense. Based upon our understandings from our most recent communications with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we believe it is not possible to reverse the not approvable status of the NDA for MT 300 and we have begun discussions regarding termination of our commercialization agreement with Valeant NA. In July 2005, we received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee. We do not believe that the withdrawal fee is payable based on our receipt of a not-approvable letter from the FDA with respect to our NDA for MT 300. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for in the agreement. We intend to vigorously defend our position under the agreement. At this time, it is not possible to determine if any withdrawal fee will be required to be paid to Valeant NA upon the ultimate resolution of this dispute.

Based upon the delays related to commercialization of MT 300 due to our receipt of the not-approvable letter for MT 300 and our efforts to address with the FDA the issues raised in that letter, we and Valeant NA had previously agreed to extend the time for certain activities under our agreement with Valeant NA that are dependent on the FDA's actions with respect to MT 300. In the event of termination of the agreement, these obligations will not be relevant. We can give no assurance that Valeant NA or Valeant International will agree to termination terms acceptable to us or that we will not be required to pay Valeant NA the withdrawal fee of $1.0 million described above. However, since the $1.0 million upfront fee is currently being accounted for as deferred revenue, a required payment to Valeant NA would have no impact on our statements of operations.

Results of Operations

Three months ended June 30, 2008 compared to the three months ended June 30, 2007

Net income/(loss) per share: Net income attributable to common stockholders for the three months ended June 30, 2008 was $13.3 million or $0.43 per share, on a diluted basis, as compared to a net loss of $(3.8) million, or $(0.13) per share, on a diluted basis, for the three months ended June 30, 2007. The net income for the three month period ended June 30, 2008 included a $1.7 million or $0.06 per share charge for non-cash stock-based compensation expense as compared to $1.1 million, or $0.04 per share for the same period of 2006.

Revenue: We recognized $33.1 million of revenue for the three months ended June 30, 2008 as compared to $11.9 million for the three months ended June 30, 2007. Licensing revenue for the three months ended June 30, 2008 was $24.5 million compared to $3.7 million for 2007. The increase in revenue was primarily due to $20.0 million in milestone payments received from GSK for the approval of, and GSK's intent to commercialize, Treximet along with $0.8 million of Treximet royalty revenue. Development revenue was $8.6 million for the three months ended June 30, 2008 compared to $8.2 million for 2007. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non-refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately $26.9 million remains in deferred revenue at June 30, 2008. Substantive milestone payments are recognized as revenue upon completion of the contractual events. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our costs associated with the billed direct costs totaled $8.0 million and $7.3 million for the three months ended June 30, 2008 and 2007, respectively. All costs associated with our development revenues are included in research and development expenses in our Statements of Operations. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Research and development: Research and development expenses increased by $3.5 million to $17.1 million for the three months ended June 30, 2008, as compared to the same period of 2007. The increase was due primarily to an increase in direct development costs for PN and PA program activities, as compared to the same period of 2007. Direct development costs for the PN program increased by $3.0 million to $13.0 million, primarily due to Phase 3 clinical trial activities and other PN product development activities pursuant to the amended AstraZeneca agreement entered into during the third quarter of 2007, as compared to the same period of 2007. Direct development costs for the PA program increased by $0.8 million to $2.0 million, while the Treximet and exploratory programs decreased by $0.6 million to $0.2 million during the second quarter of 2008, as compared to the same period of 2007. Other direct development costs and departmental expenses increased by $0.4 million primarily due to increased personnel costs, as compared to the same period of 2007. We have included in our research and development total expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, and regulatory matters.

General and administrative: General and administrative expenses increased by $0.2 million to $3.1 million for the three months ended June 30, 2008, as compared to the same period of 2007. The increase was due primarily to increased personnel costs, including reduced non-cash stock based compensation expense, as compared to the same period of 2007. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was $0.2 million for the three months ended June 30, 2008 and $0.3 million for the three months ended June 30, 2007. Investment income from bond amortization for the three month period ended June 30, 2008 totaled $0.3 million as compared to $0.4 million during the same period of 2007. Investment income decreased primarily due to declining short-term interest rates.

Six months ended June 30, 2008 compared to the six months ended June 30, 2007

Net income/(loss) per share: Net income attributable to common stockholders for the six months ended June 30, 2008 was $6.0 million or $0.19 per share, on a diluted basis, as compared to a net loss of $(5.9) million, or $(0.20) per share, on a diluted basis, for the six months ended June 30, 2007. The net income for the six months ended June 30, 2008 included a $2.7 million or $0.09 per share charge for non-cash stock-based compensation expense as compared to $2.7 million or $0.09 per share for the same period of 2007.

Revenue: We recognized total revenue of $41.0 million for the six months ended June 30, 2008 as compared to total revenue of $19.6 million for the six months ended June 30, 2007. The increase in revenue was primarily due to $20.0 million in milestone payments received from GSK for the approval of, and GSK's intent to commercialize, Treximet along with $0.8 million of Treximet royalty revenue. Other licensing revenue for the six months ended June 30, 2008 was $7.5 million compared to $7.4 million for 2007. Development revenue was $12.6 million for the six months ended June 30, 2008 compared to $12.2 million for 2007. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non-refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately $26.9 million remains in deferred revenue at June 30, 2008. Substantive milestone payments are recognized as revenue upon completion of the contractual events. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our costs associated with the billed direct costs totaled $11.2 million and $10.8 million for the six months ended June 30, 2008 and 2007, respectively. All costs associated with our development revenues are included in research and development expenses in our Statements of Operations. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Research and development: Research and development expenses increased by $9.3 million to $30.3 million for the six months ended June 30, 2008, as compared to the same period of 2007. The increase was due primarily to an increase in direct development costs for our PN program, partially offset by a decrease in direct development costs for our PA and exploratory programs, as compared to the same period of 2007. Direct development costs for the PN program increased by $9.8 million to $23.4 million, primarily due to clinical trial activities and other product development activities during the six months ended June 30, 2008, as compared to the same period of 2007. Direct development costs for the PA and exploratory programs decreased by $0.9 million to $2.9 million, as compared to the same period of 2007. Other direct development costs and departmental expenses increased by $0.4 million primarily due to increased personnel costs, as compared to the same period of 2007.We have included in our research and development total expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities and regulatory matters.

General and administrative: General and administrative expenses decreased by $0.2 million to $6.0 million for the six months ended June 30, 2008, as compared to the same period of 2007. The decrease was due primarily to reduced personnel costs and marketing research expenses, as compared to the same period of 2007. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was $0.7 and $0.6 million for the six-month periods ended June 30, 2008 and 2007, respectively. Investment income from bond amortization for the period ended June 30, 2008 totaled $0.6 million as compared to $0.9 million during the same period of 2007.

Income Taxes

We estimate an annual effective tax rate of 0% for the year ended December 31, 2008 based upon financial results and annual forecasts available at June 30, 2008. Our effective tax rate was 0% for the six month period ended June 30, 2008. However, the actual effective rate may vary depending upon actual licensing fees and milestone payments received, specifically the pre-tax book income for the year, and other factors. Income taxes have been accounted for using the liability method in accordance with SFAS 109, "Accounting for Income Taxes." Since our inception, we have incurred substantial losses and may incur substantial and recurring losses in future periods. The Tax Reform Act of 1986 (the "Act") provides for a limitation on the annual use of net operating loss and research and development tax credit carry-forwards (following certain ownership changes, as defined by the Act) that could limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Act, as a result of, among other reasons, past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because tax laws limit the time during which these carry-forwards may be applied against future taxes, we may not be able to take full advantage of these carry-forwards for federal and state income tax purposes.

We currently file income tax returns in the U.S. federal jurisdiction, and the state of North Carolina. We are no longer subject to federal or North Carolina income tax examinations by tax authorities for years before 2003. However, the loss carryforwards generated from 1996 through 2002 are subject to change, if we subsequently begin utilizing these losses in a year that is open under statute and subject to federal or North Carolina income tax examinations by tax authorities.

We adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes ("FIN 48"), on January 1, 2007 and as a result, there were no material impacts to the financial statements.

We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the six month periods ended June 30, 2008 and 2007, there were no such interest and penalties.

Liquidity and Capital Resources

Since our inception, we have financed our operations and internal growth through private placements of preferred stock and our initial public offering, resulting in cash inflows of $133.9 million. Since 2003, we have received $152.5 million from upfront and milestone payments from our collaborators. Additionally, since 2004, we have received $28.6 million of development revenue payments associated with development activities pursuant to the terms of our agreements with AstraZeneca and GSK. At June 30, 2008, cash and cash equivalents, along with short-term investments, totaled $72.2 million, a decrease of $1.7 million compared to December 31, 2007. The decrease in cash was primarily due to operating expenses for the period offset in part by cash receipts for development activities and milestone payments received pursuant to the terms of our agreements with AstraZeneca and GSK. Our cash is invested in money market funds that invest primarily in short-term, highly rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks and short-term corporate fixed income obligations and U.S. Government agency obligations.

Short-term investments are held in a managed investment account designed to increase the return on our cash. This account, which is invested as described above, is managed within our Board approved investment policy, which restricts investments to maturities of less than twelve months, limits concentration to 5% or less and requires minimum credit ratings of A1/P1, among other requirements. Because certain holdings in the managed account have maturities longer than three months, we have classified these holdings as short-term investments in our balance sheet and accounting principles require reporting such investments at market value. Any difference in market value and cost is reported in the stockholder's equity section of our financial statements as comprehensive income or loss.

We received $26.1 million in operating cash during the six months ended June 30, 2008 pursuant to the terms of our collaboration agreements with AstraZeneca and GSK. In addition, our balance sheet included a $8.6 million accounts receivable for invoiced development activities under the terms of the AstraZeneca and GSK agreements. Cash received from financing activities during the period totaled $160.3 thousand reflecting net proceeds from the exercise of stock options.

Based upon the indirect method of presenting cash flow, cash used in operating activities totaled $2.4 million for the six months ended June 30, 2008. Cash used in operating activities was $11.8 million for the six months ended June 30, 2007. Net cash used in investing activities during the six months ended June 30, 2008 totaled $4.2 million, and net cash provided by investing activities for the six months ended June 30, 2007 totaled $0.8 million reflecting investing activities associated with the sale of short-term securities. Cash required for our operating activities during 2008 is projected to increase from our 2007 requirements as a result of increased development activities. During the six-month periods ended June 30, 2008 and June 30, 2007 we recorded non-cash stock-based compensation expense of $2.7 million associated with the grant of stock options and restricted stock.

As of June 30, 2008, we had $31.2 million in cash and cash equivalents and $41.0 million in short-term investments. Our operating expenses for 2008 and 2009 are expected to increase from the level of our operating expenses in 2007 as a result of increase development activities. However, we believe that we will have sufficient cash reserves to maintain our planned level of business activities through 2009 provided that certain development expenses are received from AstraZeneca, as outlined in the agreement.

As part of our ongoing assessment of our business and liquidity needs, we regularly assess available funding options and will consider available funding opportunities as they arise. We may sell shares of common stock in the future to fund additional development activities and increase our working capital. We have filed with the Securities and Exchange Commission (SEC), and the SEC has declared effective, a shelf registration statement on Form S-3 under which we may register up to 8,540,000 shares of our common stock for sale in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to an aggregate of 540,000 of such shares, and we will not receive any of the proceeds from the sales of shares made by the selling stockholders. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

Our forecast of the period of time through which we expect that our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary as a result of a number of factors. Our future capital requirements will depend on many factors, including:

- the number and progress of our clinical trials and other trials and studies;
- our success, or any delays, in obtaining, and any delays in obtaining, regulatory approval of our product candidates and success in, and manner of, commercializing our products;
- the success of our existing collaborations and our ability to establish additional collaborations;
- the extent to which we acquire or invest in businesses, technologies or products;
- costs incurred to enforce and defend our patent claims and other intellectual rights;
- our ability to negotiate favorable terms with various contractors assisting in our trials and studies; and
- costs incurred in the defense of the class action lawsuit that is pending against us and our president and chief executive officer relating to Treximet.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The proceeds from our initial public offering, private placements and revenue from our collaboration agreements have been invested in money market funds that invest primarily in short-term, highly-rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks and short-term corporate fixed income obligations and U.S. Government and Government agency obligations. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Because of the short-term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Our management's report on internal control over financial reporting procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) is included with the financial statements reflected in Item 8 of this Annual Report on Form 10-K and is incorporated herein by reference.

No change in our internal control over financial reporting occurred during the second fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of its securities against the Company, its chairman and chief executive officer and one of its directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, the Company received the plaintiffs' amended and consolidated complaint which added two current officers of the Company as additional defendants. The Company and individual defendants filed a motion to

dismiss the amended and consolidated complaint with the Court on June 26, 2008. The Company and the individual defendants believe that the plaintiffs' allegations are without merit, and intend to defend these claims vigorously.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the pending class action lawsuit described above. Furthermore, we will have to incur expenses in connection with this lawsuit, which may be substantial. In the event of an adverse outcome, our business could be materially harmed. Moreover, responding to and defending the pending litigation will result in a significant diversion of management's attention and resources and an increase in professional fees.

Item 1A. Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

Risks Related to Our Business

We have incurred losses since inception and we may continue to incur losses for the foreseeable future. Product revenue is dependent upon the commercialization efforts of our partners, including the sales and marketing efforts of GSK relating to Treximet.

We have incurred significant losses since our inception. As of June 30, 2008, we had an accumulated deficit of approximately $121.2 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing and amount of payments that we may receive from others. We expect to continue to incur significant operating losses associated with our research and development efforts and do not know the amount or timing of product revenue we will receive as a result of sales of Treximet by GSK or sales of our other product candidates by our commercial partners. For example, GSK's inability to launch Treximet with approved promotional materials, including direct to consumer advertising, may have had an adverse impact on initial sales of the product, thus affecting our royalty revenue during the second quarter. GSK has not yet received approval of the promotional materials from the FDA, which may negatively impact our royalty revenue in the third quarter.

Our only current potential sources of revenue are the payments that we may receive pursuant to our collaboration agreements with GSK and AstraZeneca. We received the remaining regulatory milestone payments under our collaboration agreement with GSK related to Treximet payable upon FDA approval and notification of GSK's intent to commercialize Treximet, receipt of which were delayed as a result of our receipt of a second approvable letter for the product on August 1, 2007. Further, we may have to pay Valeant NA a $1.0 million withdrawal fee if we do not prevail in our current dispute with them as to whether the withdrawal fee is payable. This amount is currently reflected in our financial statements as deferred revenue and will never be recognized as revenue if repaid.

We depend heavily on the success of our product candidates, which may never be approved for commercial use. If we are unable to develop, gain approval of or commercialize those product candidates, we will never receive revenues from the sale of our product candidates.

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful development, approval and commercialization of Treximet and our current product candidates. Many factors could negatively affect our ability to obtain regulatory approval for our product candidates. For example, approval of Treximet for commercial use was significantly delayed by our receipt of two approvable letters, the first of which we received in June 2006 in which the FDA requested additional safety information on Treximet, some of which required new studies. On August 1, 2007, we received a second approvable letter from the FDA for Treximet in which the FDA requested that we further address the FDA's concern about the product's potential for genotoxicity.

In addition to the inability to obtain regulatory approval, many other factors could negatively affect the success of our efforts to develop and commercialize our product candidates, including those discussed in the risk factors that follow as well as negative, inconclusive or otherwise unfavorable results from any studies or clinical trials, such as those that we obtained with respect to MT 500, which led to our decision to discontinue development of that product candidate in 2002.

Changes in regulatory approval policy or statutory or regulatory requirements, or in the regulatory environment, during the development period of any of our product candidates may result in delays in the approval, or rejection, of the application for approval of one or more of our product candidates. If we fail to obtain approval, or are delayed in obtaining approval, of our product candidates, our ability to generate revenue will be severely impaired.

The process of drug development and regulatory approval for product candidates takes many years, during which time the FDA's interpretations of the standards against which drugs are judged for approval may evolve or change. The FDA can also change its approval policies based upon changes in laws and regulations. In addition, it can decide, based on its then current approval policies, any changes in those policies and its broad discretion in the approval process, to weigh the benefits and the risks of every drug candidate. As a result of any of the foregoing, the FDA may decide that the data we submit in support of an application for approval of a drug candidate are insufficient for approval. Further, changes in policy or interpretation may not be the subject of published guidelines and may therefore be difficult to evaluate. For example, the FDA has not recently published guidelines for the approval of new migraine therapies, and we have had to rely on periodic guidance from the FDA obtained in conversations and other meetings, the content of which may be subject to significant modification over the period of a drug's development program. There is also the risk that we and the FDA may interpret such guidance differently.

Further, additional information about the potential risks of marketed drugs may affect the regulatory approval environment, or the FDA's approval policies, for new product candidates. For example, in February 2005 an advisory committee convened by the FDA met to address the potential cardiovascular risks of COX-2 selective NSAIDs and related drugs in response to disclosures made about possible adverse effects from the use of some of these drugs. On April 7, 2005 the FDA issued a Public Health Advisory, or the Advisory, based, in part, upon the recommendations of the advisory committee. The Advisory stated that it would require that manufacturers of all prescription products containing NSAIDs provide warnings regarding the potential for adverse cardiovascular events as well as life-threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to the FDA advisory committee meeting in February 2005, the FDA has indicated that long-term studies evaluating cardiovascular risk will be required for approval of new NSAID products that may be used on an intermittent or chronic basis. For example, we believe that long-term cardiovascular safety studies will be required for NDA approval of any oral lornoxicam product candidate we may develop. We do not know to what extent the FDA's actions may otherwise adversely affect or delay the approvability of our PN or other product candidates that contain NSAIDs.

If we, or our current or future collaborators, do not obtain and maintain required regulatory approvals for one or more of our product candidates, we will be unable to commercialize those product candidates. Further, if we are delayed in obtaining or unable to obtain, any required approvals, our collaborators may terminate, or be entitled to terminate, their agreements with us or reduce or eliminate their payments to us under these agreements or we may be required to pay termination payments under these agreements.

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products in the United States. In order to market our products abroad, we must comply with extensive regulation by foreign governments. If we are unable to obtain and maintain FDA and foreign government approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing that product candidate. Except for Treximet, which was approved for commercial sale in the U.S. on April 15, 2008, none of our other product candidates have been approved for sale in the U.S. or any foreign market and they may never be approved. For example, we received two approvable letters relating to our NDA for Treximet which communicated FDA's concerns that delayed marketing approval. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. In June 2006, we received the first approvable letter in which the FDA requested additional safety information on Treximet, and in August 2007, we received a second approvable letter in which the FDA requested that we address their concern about the potential implications from one preclinical in vitro chromosomal aberration study in which a signal for genotoxicity was seen for the combination of naproxen sodium and sumatriptan. We have also previously received not-approvable letters from the FDA relating to our NDAs for MT 100 and MT 300.

In the U.S., a separate NDA or supplement must be filed with respect to each indication for which marketing approval of a product is sought. Each NDA, in turn, requires the successful completion of preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials demonstrating the safety and efficacy of the product for that particular indication. We may not receive regulatory approval of any of the NDAs that we file with the FDA or of any approval applications we may seek in the future outside the U.S.

Further, our current or future collaboration agreements may terminate, or require us to make certain payments to our collaborators, or our collaborators may have the right to terminate their agreements with us or reduce or eliminate their payments to us under these agreements, based on our inability to obtain, or delays in obtaining, regulatory approval for our product candidates. For

example, under our PN collaboration agreement with AstraZeneca, AstraZeneca has the right to terminate the agreement if certain delays occur or specified development and regulatory objectives are not met. Both AstraZeneca and GSK have the right to terminate their respective agreement with us upon 90 days notice for any reason. If we or our contract manufacturers do not maintain required regulatory approvals, we may not be able to commercialize our products. Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and is subject to continuous review. The FDA may also require us to conduct additional post-approval studies. These post-approval studies may include carcinogenicity studies in animals or further human clinical trials. The later discovery of previously unknown problems with the product, manufacturer or manufacturing facility may result in criminal prosecution, civil penalties, recall or seizure of products, or total or partial suspension of production, as well as other regulatory action against our product candidates or us. If approvals are withdrawn for a product, or if a product is seized or recalled, we would be unable to sell that product and therefore would not receive any revenues from that product.

We and our contract manufacturers are required to comply with the applicable FDA current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our product candidates, and are subject to additional FDA inspection. We, or our third-party manufacturers, may not be able to comply with cGMP regulations or other FDA regulatory requirements, which could result in a delay or an inability to manufacture the products. If we or our partners wish or need to identify an alternative manufacturer, delays in obtaining FDA approval of the alternative manufacturing facility could cause an interruption in the supply of our products.

Labeling and promotional activities are subject to scrutiny by the FDA and state regulatory agencies and, in some circumstances, the Federal Trade Commission. FDA enforcement policy prohibits the marketing of unapproved products as well as the marketing of approved products for unapproved, or off-label, uses. These regulations and the FDA's interpretation of them may limit our or our partners' ability to market products for which we gain approval. Failure to comply with these requirements can result in federal and state regulatory enforcement action. Further, we may not obtain the labeling claims we or our partners believe are necessary or desirable for the promotion of our product candidates.

Our reliance on collaborations with third parties to develop and commercialize our products is subject to inherent risks and may result in delays in product development and lost or reduced revenues, restricting our ability to commercialize our products and adversely affecting our profitability.

Under our current strategy, and for the foreseeable future, we expect to depend upon collaborations with third parties to develop our product candidates and we expect to depend substantially upon third parties to commercialize our products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and any future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and intend in the future to continue to engage, contract manufacturers and clinical trial investigators.

In addition, although not a primary component of our current strategy, the identification of new compounds or product candidates for development has led us, and may continue to require us, to enter into license or other collaborative agreements with others, including pharmaceutical companies and research institutions. Such collaborative agreements for the acquisition of new compounds or product candidates would typically require us to pay license fees, make milestone payments and/or pay royalties. Furthermore, these agreements may result in our revenues being lower than if we developed our product candidates ourselves and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their agreements with us or reduce their payments to us under those agreements on limited or no notice and for reasons outside of our control. We currently have a collaboration with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology, including Treximet, in the U.S., a global collaboration with AstraZeneca for the development and commercialization of proprietary combinations of gastroprotective agents and naproxen, and a collaboration with Valeant NA in the U.S. for the development and commercialization of MT 300. In these collaboration agreements, our collaborators have the right to terminate the agreement upon a default by us. In addition, GSK and AstraZeneca are entitled to terminate their respective agreements with us upon 90 days' notice for any reason. Additionally, both GSK and AstraZeneca have the right to reduce the royalties on net sales of products payable to us under their respective agreements if generic competitors attain a pre-determined share of the market for products marketed under the agreements, or if either GSK or AstraZeneca must pay a royalty to one or more third parties for rights it licenses from those third parties to commercialize products marketed under the agreements. AstraZeneca is also entitled to terminate its agreement with us if certain delays occur or specified development or regulatory objectives are not met. Valeant NA is entitled to terminate its agreement with us and a $1.0 million withdrawal fee payable by us in the event we choose to withdraw the NDA if we determine that additional studies or data that are required by the FDA for approval of the NDA would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300. Due to our belief that the FDA will not approve the NDA for MT 300, we began discussions with Valeant NA regarding termination of our agreement. Valeant NA has demanded payment of the $1.0 million withdrawal fee, which POZEN is disputing.

If our current or future licensees exercise termination rights they may have, or if these license agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and/or commercialize our product candidates. Moreover, any future collaborations or license arrangements we may enter into may not be on terms favorable to us.

A further risk we face with our collaborations is that business combinations and changes in the collaborator or their business strategy may adversely affect their willingness or ability to complete their obligations to us.

Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allow them discretion in electing whether to pursue various regulatory, commercialization and other activities or with respect to the timing of the development, such as our agreement with GSK under which GSK determined, among other things, the exact formulation and composition of the product candidates using our MT 400 technology for use in the Treximet clinical trials. Similarly, under our agreement with AstraZeneca, AstraZeneca has the right to manufacture clinical trial material itself or through a third party. If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre-clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated. Any delay or termination of clinical development or commercialization, such as the delay in FDA approval we experienced as a result of approvable letters we received from the FDA in June 2006 and August 2007 related to our Treximet NDA, would delay or possibly eliminate our potential product revenues. Further, our collaborators may be able to exercise control, under certain circumstances, over our ability to protect our patent rights under patents covered by the applicable collaboration agreement. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under their respective agreements and would have exclusive control over such enforcement litigation.

Other risks associated with our collaborative and contractual arrangements with others include the following:

- we may not have day-to-day control over the activities of our contractors or collaborators;
- our collaborators may fail to defend or enforce patents they own on compounds or technologies that are incorporated into the products we develop with them;
- third parties may not fulfill their regulatory or other obligations;
- we may not realize the contemplated or expected benefits from collaborative or other arrangements; and
- disagreements may arise regarding a breach of the arrangement, the interpretation of the agreement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development of our product candidates and/or the commercialization of our products or reduction in the milestone payments we receive from our collaborators, or could result in our not being able to commercialize our products. Further, disagreements with our contractors or collaborators could require or result in litigation or arbitration, which would be time-consuming and expensive. Our ultimate success may depend upon the success and performance on the part of these third parties. If we fail to maintain these relationships or establish new relationships as required, development of our product candidates and/or the commercialization of our products will be delayed or may never be realized.

A collaborator may withdraw support or cease to perform work on our product candidates if the collaborator determines to develop its own competing product candidate or other product candidates instead.

We have entered into collaboration and license agreements, and expect to continue to enter into such agreements, with companies that have products and are developing new product candidates that compete or may compete with our product candidates or which have greater commercial potential. If one of our collaborators should decide that the product or a product candidate that the collaborator is developing would be more profitable for the collaborator than our product candidate covered by the collaboration or license agreement, the collaborator may withdraw support for our product candidate or may cease to perform under our agreement. In the event of a termination of the collaborator's agreement upon such cessation of performance, we would need to negotiate an agreement with another collaborator in order to continue the development and commercialization efforts for the product candidate. If we were unsuccessful in negotiating another agreement, we might have to cease development activities of the particular product candidate. For example, our development and commercialization agreement with GSK is subject to this risk. GSK has publicly disclosed that it is exploring the development of several compounds for the treatment of migraine. If GSK decides to focus its development and commercialization efforts on its own products rather than continuing to commercialize Treximet or work with us on any other product candidates that may be developed under the agreement, it has the ability to terminate our agreement upon 90 days' written notice. In such a case, we would need to enter into a new development and commercialization agreement and would need to

start the development process all over again. If we were able to negotiate a new development and commercialization agreement to develop our MT 400 technology, which is not certain, we would face delays and redundant expenses in that development.

We need to maintain current agreements and enter into additional agreements with third parties that possess sales, marketing and distribution capabilities, or establish internally the capability to perform these functions, in order to successfully market and sell our future drug products.

We have no sales or distribution personnel or capabilities. If we are unable to maintain current collaborations or enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to provide those capabilities, or, alternatively, we are unable to develop internally sales and distribution capabilities, we will not be able to successfully commercialize our products. To the extent that we enter into marketing and sales agreements with third parties, such as our agreement with GSKwhich gives GSK responsibility for marketing and selling Treximet in the United States, our revenues, if any, will be affected by the sales and marketing efforts of those third parties. Further, we cannot guarantee that, should we elect to develop our own sales and distribution capabilities, we would have sufficient resources to do so, or would be able to hire the qualified sales and marketing personnel we would need.

Because we do not believe it is possible to convince the FDA to reverse its conclusion as stated in its not-approvable letter for MT 300, we do not expect to receive any revenue from sales of MT 300 in the U.S.

In October 2003, we received a not-approvable letter from the FDA related to our NDA for MT 300. The letter was issued based on the FDA's conclusion that we had not submitted substantial evidence of effectiveness for MT 300 as an acute treatment for migraine. The FDA noted that, although MT 300 provided a statistically significant improvement over placebo on the pre-defined endpoint of sustained pain relief at 24 hours post dose as well as relief of pain at two hours post dose, MT 300 failed to achieve statistical significance versus placebo for the relief of all of the ancillary symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Further, the FDA noted that the incidence of nausea, one of the associated symptoms of migraine, was statistically significantly higher following MT 300 treatment versus placebo at two hours. After our receipt of the not-approvable letter, we had continuing communications with the FDA regarding the MT 300 NDA. Based upon our understandings from our most recent communications with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the MT 300 NDA. Therefore, we do not believe that we will receive any revenue from sales of MT 300 in the U.S.

We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, and clinical trials for our product candidates. Any negative or unanticipated results, unforeseen costs or delays in the conduct of these studies or trials, or the need to conduct additional studies or trials or to seek to persuade the FDA to evaluate the results of a study or trial in a different manner, could cause us to discontinue development of a product candidate or reduce, delay or eliminate our receipt of potential revenues for one or more of our product candidates and adversely affect our ability to achieve profitability.

Generally, we must demonstrate the efficacy and safety of our product candidates before approval to market can be obtained from the FDA or the regulatory authorities in other countries. Our existing and future product candidates are and will be in various stages of clinical development. Depending upon the type of product candidate and the stage of the development process of a product candidate, we will need to complete preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, as well as clinical trials, on these product candidates before we submit marketing applications in the United States and abroad. These studies and trials can be very costly and time-consuming. For example, long-term cardiovascular safety studies, such as those the FDA has indicated will be required for approval of certain product candidates containing NSAIDs, typically take approximately three years. In addition, we rely on third parties to perform significant aspects of our studies and clinical trials, introducing additional sources of risk into our development programs.

It should be noted that the results of any of our preclinical and clinical trial testing are not necessarily predictive of results we will obtain in subsequent or more extensive clinical trials or testing. This may occur for many reasons, including, among others, differences in study design, including inclusion/exclusion criteria, the variability of patient characteristics, including patient symptoms at the time of study treatment, the larger scale testing of patients in later trials, or differences in formulation or doses of the product candidate used in later trials. For example, our results from the first of our two Phase 3 pivotal clinical trials of Treximet differed from the results of our second Phase 3 clinical trial and from the Phase 2 proof-of-concept trial of MT 400 that we conducted prior to entering into our collaboration with GSK. Whereas in the Phase 2 trial statistical significance was reached at two hours over placebo in the relief of all associated symptoms of migraine (nausea, photophobia and phonophobia), in the first Phase 3 study Treximet failed to achieve statistical significance at two hours compared to placebo in the relief of nausea. In the second Phase 3 pivotal clinical trial, Treximet demonstrated superiority over the individual components measured by sustained pain-free response ($p<0.001$ vs. naproxen; $p=0.009$ vs. sumatriptan) and met all other regulatory endpoints versus placebo.

The successful completion of any of our clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that is unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Further, even though we may have completed all clinical trials for a product candidate that were planned for submission in support of a marketing application, we may be required to conduct additional clinical trials, studies or investigations or to submit additional data to support our marketing applications. In addition, we and/or our marketing or development partners may determine that pre-approval marketing support studies should be conducted. Unanticipated adverse outcomes of such studies, including recognition of certain risks to human subjects, could a have material impact on the approval of filed or planned market applications or could result in limits placed on the marketing of the product. We may also determine from time to time that it would be necessary to seek to provide justification to the FDA or other regulatory agency that would result in evaluation of the results of a study or clinical trial in a manner that differs from the way the regulatory agency initially or customarily evaluated the results. In addition, we may have unexpected results in our preclinical or clinical trials or other studies that require us to reconsider the need for certain studies or trials or cause us to discontinue development of a product candidate. For example, in reviewing our NDA for Treximet, the FDA expressed concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan.

Once submitted, an NDA requires FDA approval before the product described in the application can be distributed or commercialized. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, the FDA requested additional safety information on Treximet in the approvable letter we received in June 2006 relating to our NDA for Treximet, which required conduct of additional studies, and in August 2007, we received a second approvable letter in which the FDA raised an additional concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan.

Further, although we believe that we provided the necessary data to support approval of the NDAs for MT 100, our proprietary combination of metoclopramide hydrochloride and naproxen sodium, and MT 300, the FDA issued not-approvable letters for the MT 100 and MT 300 NDAs in May 2004 and October 2003, respectively, and based upon our understandings from our most recent communication with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the NDA for MT 300. In addition, based upon our receipt of the not approvable letter for MT 100 and the outcome of an August 2005 FDA Advisory Committee meeting relating to the potential risk of tardive dyskinesia associated with the use of one of the components of MT 100, we made the decision to discontinue further development of MT 100 and have withdrawn the MAA for the product in the U.K.

The FDA may also require data in certain subpopulations, such as pediatric use, or, if such studies were not previously completed, may require long-term carcinogenicity studies, prior to NDA approval, unless we can obtain a waiver of such a requirement. We face similar regulatory hurdles in other countries to those that we face in the U.S.

Our costs associated with our human clinical trials vary based on a number of factors, including:

- the order and timing of clinical indications pursued;
- the extent of development and financial support from collaborative parties, if any;
- the need to conduct additional clinical trials or studies;
- the number of patients required for enrollment;
- the difficulty of obtaining sufficient patient populations and clinicians;
- the difficulty of obtaining clinical supplies of our product candidates; and
- governmental and regulatory delays.

We currently depend and will in the future depend on third parties to manufacture our product candidates. If these manufacturers fail to meet our requirements or any regulatory requirements, the product development and commercialization of our product candidates will be delayed.

We do not have, and have no plans to develop, the internal capability to manufacture either clinical trial or commercial quantities of products that we may develop or have under development. We rely upon third-party manufacturers and our partners to supply us with our product candidates. We also need supply contracts to sell our products commercially. There is no guarantee that manufacturers that enter into commercial supply contracts with us will be financially viable entities going forward, or will not otherwise breach or terminate their agreements with us. If we do not have the necessary commercial supply contracts, or if our current manufacturer is, or any of our future manufacturers are, unable to satisfy our requirements or meet any regulatory requirements, and we are required to find alternative sources of supply, there may be additional costs and delays in product development and commercialization of our product candidates or we may be required to comply with additional regulatory requirements.

If our competitors develop and commercialize products faster than we do or if their products are superior to ours, our commercial opportunities will be reduced or eliminated.

Our product candidates will have to compete with existing and any newly developed migraine therapies or therapies for any newly developed product candidates for the treatment of other diseases. There are also likely to be numerous competitors developing new products to treat migraine and the other diseases and conditions for which we may seek to develop products in the future, which could render our product candidates or technologies obsolete or non-competitive. For example, our primary competitors will likely include large pharmaceutical companies (including, based upon their current migraine portfolios, GSK, Merck & Co., AstraZeneca, Johnson & Johnson, Pfizer, Inc. and Endo Pharmaceuticals), biotechnology companies, universities and public and private research institutions. The competition for our PN products that receive regulatory approval will come from the oral NSAID market, or more specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC™), combinations of NSAIDs and PPIs taken as separate pills and the only remaining COX-2 inhibitor, Celebrex®.

Based upon their drug product and pipeline portfolios and the overall competitiveness of our industry, we believe that we face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology. Our competitors, either alone or with collaborative parties, may also succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do.

Many of these competitors, either alone or together with their collaborative parties, also have significantly greater experience than we do in:

- developing product candidates;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of product candidates; and
- manufacturing and marketing products.

Accordingly, our actual or potential competitors may succeed in obtaining patent protection, receiving FDA or other regulatory approval or commercializing products where we cannot or before we do. Any delays we encounter in obtaining regulatory approvals for our product candidates, such as we experienced as a result of the approvable letters we received from the FDA in June 2006 and August 2007 relating to the Treximet NDA, and as we have previously experienced as a result of the not-approvable letters we received from the FDA on MT 100 and MT 300, increase this risk. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive any revenues from sales of products or may not receive sufficient revenues to achieve profitability.

If there is an adverse outcome in the securities class action lawsuits that have been filed against us or our current or former directors and officers, our business may be materially harmed. Further, defending against these lawsuits may be expensive and will divert the attention of our management.

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of our securities against us, our chairman and chief executive officer and one of our directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, the Company received the plaintiffs' amended and consolidated complaint which added two current officers of the Company as additional defendants. The Company and individual defendants filed a motion to dismiss the amended and consolidated complaint with the Court on June 26, 2008. The Company and the individual defendants believe that the plaintiffs' allegations are without merit, and intend to defend these claims vigorously.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the pending class action lawsuit described above. Furthermore, we will have to incur expenses in connection with this lawsuit, which may be substantial. In the event of an adverse outcome, our business could be materially harmed. Moreover, responding to and defending the pending litigation will result in a significant diversion of management's attention and resources and an increase in professional fees.

If we are unable to protect our patents or proprietary rights, or if we are unable to operate our business without infringing the patents and proprietary rights of others, we may be unable to develop our product candidates or compete effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our ability, and the ability of our licensors, to obtain and to keep protection for our products and technologies under the patent laws of the United States and other countries, so that we can stop others from using our inventions. Our success also will depend on our ability to prevent others from using our trade secrets. In addition, we must operate in a way that does not infringe, or violate, the patent, trade secret and other intellectual property rights of other parties.

We cannot know how much protection, if any, our patents will provide or whether our patent applications will issue as patents. The breadth of claims that will be allowed in patent applications cannot be predicted and neither the validity nor enforceability of claims in issued patents can be assured**.** If, for any reason, we are unable to obtain and enforce valid claims covering our products and technology, we may be unable to prevent competitors from using the same or similar technology or to prevent competitors from marketing identical products. In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our products, any patents that protect our product candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us.

In certain territories outside the U.S., our issued patents may be subject to opposition by competitors within a certain time after the patent is issued. Such opposition proceedings and related appeals may not be resolved for several years, and may result in the partial or total revocation of the issued patent. For example, in October 2005 oppositions were filed against our issued European patent for MT 400 by Merck & Co., Inc. and Almirall Prodesfarma asserting that the European patent should not have been granted. As a result of these oppositions and subsequent proceedings, the European Patent Office found that claims relating to combinations of sumatriptan and naproxen for the treatment of migraine were valid. However, broader claims relating to certain other 5-HT 1B/1D agonists and long-acting NSAIDs were held to be insufficiently supported by the presently available technical evidence.

We may need to submit our issued patents for amendment or reissue if we determine that any claims within our patents should not have been issued. While such a submission may be based on our view that only specified claims should not have been granted to us, there can be no assurance that a patent examiner will not determine that additional claims should not have been granted to us. Such was the case with one of our patents covering MT 100, which we submitted for reissue after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued. In April 2006, we received an office action on the reissue application and, consistent with our decision not to devote further resources to the development of this product in the U.S., the reissue application was abandoned in January 2007.

We may need to license rights to third party patents and intellectual property to continue the development and marketing of our product candidates. If we are unable to acquire such rights on acceptable terms, our development activities may be blocked and we may be unable to bring our product candidates to market.

We may enter into litigation to defend ourselves against claims of infringement, assert claims that a third party is infringing one or more of our patents, protect our trade secrets or know-how, or determine the scope and validity of others' patent or proprietary rights. As a result of such litigation, our patent claims may be found to be invalid, unenforceable or not of sufficient scope to cover the activities of an alleged infringement. With respect to some of our product candidates, under certain circumstances, our development or commercialization collaborators have the first right to enforce our patents and would have exclusive control over such enforcement litigation. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under their respective agreements.

If we are found to infringe the patent rights of others, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and marketing activities. Additionally, if we or our development or commercialization collaborator seek to enforce our patents and are unsuccessful, we may be subject to claims for bringing a failed enforcement action, including claims alleging various forms of antitrust violations (both state and federal) and unfair competition. If we are found to be liable for such claims, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and commercialization activities. Even if we are successful in defending any such claims of infringement or in asserting claims against third parties, such litigation is expensive, may have a material effect on our operations, and may distract management from our business operations. Regardless of its eventual outcome, any lawsuit that we enter into may consume time and resources that would impair our ability to develop and market our product candidates.

We have entered into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and, as a result, we may not be able to protect our rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how. Also, many of our scientific and management personnel were previously employed by competing companies. As a result, such companies may allege trade secret violations and similar claims against us.

If we fail to acquire, develop and commercialize additional products or product candidates, or fail to successfully promote or market approved products, we may never achieve profitability.

As part of our business strategy, we plan to identify, self-invent and/or acquire product candidates or approved products in areas in which we possess particular knowledge. Because we do not directly engage in basic research or drug discovery, we may rely upon third parties to sell or license product opportunities to us. Other companies, including some with substantially greater financial, marketing and sales resources, are competing with us to acquire such products and product candidates. We may not be able to acquire rights to additional products or product candidates on acceptable terms, if at all. In addition, if we acquire new products or product candidates with different marketing strategies, distribution channels and bases of competition than those of our current product candidates, we may not be able to compete favorably in those product categories.

None of our products may be accepted by the market.

The commercial success of our other product candidates depends upon the acceptance of these products in the marketplace. Even if a product displays a favorable efficacy and safety profile in clinical trials, market acceptance of a product will not be known until after it is launched and a product may not generate the revenues that we anticipate. The degree of market acceptance will depend upon a number of factors, including:

- the acceptance by physicians and third-party payors of Treximet as an alternative to Imitrex and other therapies;
- the receipt and timing of regulatory approvals;
- the availability of third-party reimbursement;
- the indications for which the product is approved;
- the rate of adoption by healthcare providers;
- the rate of product acceptance by target patient populations;
- the price of the product relative to alternative therapies;
- the availability of alternative therapies;
- the extent and effectiveness of marketing efforts by our collaborators, and third-party distributors and agents;
- the existence of adverse publicity regarding our products or similar products; and
- the extent and severity of side effects as compared to alternative therapies.

If we do not receive adequate third-party reimbursements for our future products, our revenues and profitability will be reduced.

Our ability to commercialize our product candidates successfully will depend, in part, on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the U.S., private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of a newly approved healthcare product. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payors for use of our products, our products may fail to achieve market acceptance.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payors to contain or reduce the costs of healthcare through various means. We expect that a number of federal, state and foreign proposals will seek to control the cost of drugs through governmental regulation. We are unsure of the form that any healthcare reform legislation may take or what actions federal, state, foreign and private payors may take in response to any proposed reforms. Therefore, we cannot predict the effect of any implemented reform on our business.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

The testing and marketing of pharmaceutical products entails an inherent risk of product liability. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling our future products. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to limit the commercialization of our product candidates. We have product liability insurance that covers our commercialized product and human clinical trials in an amount equal to up to $10.0 million annual aggregate limit with a $0.1 million deductible per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. However, insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We will explore, on an on-going basis, expanding our insurance coverage related to the sale of Treximet and for the inclusion of future marketed products when we obtain marketing approval for such products and commercial sales of such products begin. However, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may be harmed or fail.

We may need additional funding and may not have access to capital. If we are unable to raise capital when needed, we may need to delay, reduce or eliminate our product development or commercialization efforts.

In the future, we may need to raise additional funds to execute our business strategy. We have incurred losses from operations since inception and we may continue to incur additional operating losses. Our actual capital requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the progress of preclinical studies, clinical and other testing or the need conduct additional trials, studies or other testing;
- the time and cost involved in obtaining any regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the timing of our receipt, if any, of milestone payments and royalties under collaborative agreements;
- the effect of changes and developments in, or termination of, our collaborative, license and other relationships;
- the terms and timing of any additional collaborative, license and other arrangements that we may establish; and
- our ability to arrange for the commercialization of our product candidates.

Our operating expenses for the year ended December 31, 2007 totaled $51.4 million, including non-cash compensation expense of $4.3 million related to stock options and other stock-based awards, primarily associated with our adoption of SFAS No. 123(R) on January 1, 2006. For fiscal years 2005 through 2007, our average annual operating expenses (including average non-cash deferred compensation of $3.6 million) were $38.2 million. We will continue discussions with AstraZeneca on the timing and scope of marketing studies to support the commercialization of PN 400. These marketing studies may impact revenue and expenses for the

2008 year. As of June 30, 2008, we had an aggregate of $72.2 million in cash and cash equivalents and short-term investments. If our operating expenses for 2008 and 2009 remain at the level of our operating expenses in 2007, we believe that we will have sufficient cash reserves to maintain that level of business activities through 2009 provided certain increased development expenses are paid by AstraZeneca, as outlined in the agreement. However, our expenses might increase during that period beyond currently expected levels if we decide to, or any regulatory agency requires us to, conduct additional clinical trials, studies or investigations for any of our product candidates, including in connection with the agency's consideration, or reconsideration, of our regulatory filings for our product candidates. In addition, we may be required to pay Valeant NA a withdrawal fee of $1.0 million if we do not prevail in our current dispute with them as to whether a withdrawal fee is payable under our MT 300 collaboration agreement.

We may be unable to raise additional equity funds when we desire to do so due to unfavorable market conditions in our industry or generally, or other unforeseen developments in our business. Further, we may not be able to find sufficient debt or equity funding, if at all, on acceptable terms. If we cannot, we may need to delay, reduce or eliminate research and development programs and therefore may not be able to execute our business strategy. Further, to the extent that we obtain additional funding through collaboration and licensing arrangements, it may be necessary for us to give up valuable rights to our development programs or technologies or grant licenses on terms that may not be favorable to us.

The sale by us of additional equity securities or the expectation that we will sell additional equity securities may have an adverse effect on the price of our common stock.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our research and development efforts.

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an amended and restated employment agreement with us on March 14, 2006, which was amended on September 28, 2007, for a three-year term with automatic one-year renewal terms. We have also entered into employment agreements with certain of our other key management personnel, which provide for one or two-year terms with automatic one-year renewal terms which were amended on September 28, 2007. If we should lose the services of Dr. Plachetka, or are unable to replace the services of our other key personnel who may leave the Company, such as Dr. Marshall E. Reese, Executive Vice President, Product Development, or William L. Hodges, Senior Vice President Finance and Administration and Chief Financial Officer or if we fail to recruit other key scientific personnel, we may be unable to achieve our business objectives. Dr. Reese has informed the Company of his intention to retire some time in the next 12 to 24 months. The Company anticipates an orderly transition of Dr. Reese's responsibilities to other key POZEN employees upon his retirement. There is intense competition for qualified scientific personnel. Since our business is very science-oriented, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business.

Factors That May Affect Our Stockholders

Our stock price is volatile, which may result in significant losses to stockholders.

There has been significant volatility in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include:

- fluctuations in our operating results;
- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- commercial success of Treximet and our other products in the marketplace once approved;
- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners;

- announcements by our collaborative partners regarding our products or product candidates;
- developments in new or pending litigation;
- public concern as to the safety and efficacy of our products; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors, including the sale or attempted sale of a large amount of our common stock into the market. From October 16, 2000, when our common stock began trading on The National Market (now known as The NASDAQ Global Market), through June 30, 2008, the high and low sales prices of our common stock ranged from $2.25 to $21.75. Broad market fluctuations may also adversely affect the market price of our common stock.

Sales of substantial amounts of our common stock in the public market could depress our stock price.

We have not sold shares of common stock in a public offering since our initial public offering in October 2000. Accordingly, we have a relatively small number of shares that are traded in the market and four of our stockholders and their affiliates beneficially hold approximately 30% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. For example, our chief executive officer and one of our directors may sell up to an aggregate of 1,180,000 shares pursuant to Rule 10b5-1 trading plans. Sales under those plans began in October 2006. Further, stockholders' ownership will be diluted if we raise additional capital by issuing equity securities. We have filed with the SEC, and the SEC has declared effective, a shelf registration statement on Form S-3 under which we may offer up to 8,540,000 shares of our common stock for sale to the public in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to 540,000 of such shares, and we would not receive any of the proceeds from sales of those shares.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management.

Provisions of our charter and bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change the direction or management of POZEN. For example, these provisions:

- authorize the issuance of "blank check" preferred stock without any need for action by stockholders;
- provide for a classified board of directors with staggered three-year terms;
- require supermajority stockholder approval to effect various amendments to our charter and bylaws;
- eliminate the ability of stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Further, in January 2005 our board of directors adopted a stockholder rights plan, similar to plans adopted by many other publicly-traded companies. The stockholder rights plan is intended to deter an attempt to acquire us in a manner or on terms not approved by our board of directors.

Item 4. Submission of Matters to a Vote of Security Holders

Our annual meeting of stockholders was held on May 6, 2008. There were present at the annual meeting of stockholders in person or by proxy stockholders holding an aggregate of 26,747,099 shares of our common stock out of a total number of 29,737,799 shares of common stock issued and outstanding and entitled to vote at the meeting. Our stockholders voted on two matters, as follows:

1. The stockholders elected three Class II directors to each serve for a three year term (until our 2011 annual meeting of stockholders and until their successors have been duly elected and qualified) by the following votes (there were no abstentions or broker non-votes in connection with the election of the Class II directors):

	Number of Shares of Common Stock	
	For:	**Withheld:**
Arthur S. Kirsch	26,632,482	114,617
Kenneth B. Lee, Jr.	26,588,061	159,038
Bruce A. Tomason	26,605,620	141,479

The other directors whose terms of office as director continued after the meeting are as follows: John R. Plachetka, Pharm.D, James J. Mauzey, Jacques F. Rejeange, Paul J. Rizzo and Peter J. Wise, M.D.

2. The stockholders ratified the appointment of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2008 by the following votes (there were no broker non-votes in connection with the ratification of our independent auditor):

Number of Shares of Common Stock		
For:	**Against:**	**Abstain:**
26,678,051	48,397	20,651

Item 6. Exhibits

Exhibit Number	Description
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

POZEN Inc.
(Registrant)

July 29, 2008 By: /s/ JOHN R. PLACHETKA
John R. Plachetka
President and Chief Executive Officer

July 29, 2008 By: /s/ WILLIAM L. HODGES
William L. Hodges
Chief Financial Officer

July 29, 2008 By: /s/ JOHN E. BARNHARDT
John E. Barnhardt
Principal Accounting Officer

EXHIBIT INDEX

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32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

EXHIBIT 31.1

Section 302 Certification

I, John R. Plachetka**,** certify that:

1. I have reviewed this Form 10-Q of POZEN Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 29, 2008

/s/ John R. Plachetka
John R. Plachetka, Pharm.D.
President and Chief Executive Officer
(principal executive officer)

EXHIBIT 31.2

Section 302 Certification

I, William L. Hodges, certify that:

1. I have reviewed this Form 10-Q of POZEN Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 29, 2008

/s/ William L. Hodges
William L. Hodges
Senior Vice President, Finance and Administration and
Chief Financial Officer

EXHIBIT 32.1

CEO CERTIFICATION PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

(18 U.S.C. SECTION 1350)

In connection with Form 10-Q of POZEN Inc. (the "Company"), as filed with the Securities and Exchange Commission (the "Report"), I, John R. Plachetka, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 29, 2008

/s/ John R. Plachetka
John R. Plachetka, Pharm.D.
Chief Executive Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CFO CERTIFICATION PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

(18 U.S.C. SECTION 1350)

In connection with Form 10-Q of POZEN Inc. (the "Company") , as filed with the Securities and Exchange Commission (the "Report"), I, William L. Hodges, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 29, 2008

/s/ William L. Hodges
William L. Hodges
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.